



Research Article

A RANDOMISED CLINICAL CONTROL STUDY TO EVALUATE THE EFFICACY OF *SHODHITA KUCHLA* POWDER (PURIFIED *STRYCHNOS NUX-VOMICA* L.) AND *BRAHMI* EXTRACT (*BACOPA MONNIERI* L. PENNELL) ON *KLAIBYA* (*DHWAJBHANG*) W.S.R. TO ERECTILE DYSFUNCTION

Deepak Verma^{1*}, Ashwini Kumar Sharma², Megha Shukla³

¹Assistant Professor, PG Department of Dravyaguna Vigyan, Dayanand Ayurved College, Jalandhar, Punjab, India.

²Associate Professor, PG Department of Dravyagun Vigyan, MMM Govt. Ayurved College, Udaipur, Rajasthan, India.

³PG Scholar, PG Department of Kriya Sharir, DSRRAU, University College of Ayurveda, Jodhpur, Rajasthan, India.

Article info

Article History:

Received: 29-09-2021

Revised: 05-10-2021

Accepted: 28-10-2021

Published: 15-11-2021

KEYWORDS:

Erectile Dysfunction, *Klaibya*, *Vajikarana*, *Sushruta*.

ABSTRACT

Klaibya is defined in Ayurveda as the inability to achieve and maintain sufficient rigidity in the penis, which is essential for his sexual urges or the needs of his female partner during sexual activity. *Chakrapani* limits the concept of *Klaibya* to merely erectile dysfunction. *Dhwajbhanga*, according to *Acharya Sushruta*, is a form of *Klaibya* caused by excessive coitus. The standard initial evaluation of a man experiencing ED is conducted in person and involves sexual, medical, and psychosocial histories, as well as laboratory tests comprehensive enough to identify comorbid diseases that may predispose the patient to ED and may contraindicate particular treatments. Properties of Ayurvedic drug; *Kuchla* (*Strychnos nux-vomica*) in classical text *Rasatarangani* as therapeutic of *Klaibya* (ED) and *Brahmi* (*Bacopa monnieri*) is well known *Medhya* drug that works on neuro- psychological disorders. The current study evaluated the effects of *Kuchla* and *Brahmi* on 36 erectile dysfunction patients, having 30 of them completing the trial. The patients were categorized into two parts: Group A administered an ED 250 capsule (Hypothetical) once a day (250mg) with milk, and Group B received a placebo once a day with milk HS for 30 days, followed by another 30 days.

INTRODUCTION

Individuals can recognise the evolution of research from the primordial stage to the present stage by reassessing a study. A historical perspective allows us to comprehend the virtues and drawbacks of science in a certain sector, allowing us to plan for its advancement in the present and future. Ayurveda assists in living a long and healthy life, which is necessary for achieving *Purushartha Chatusthaya*, the ultimate objective of human beings. *Kama*; being one of them, is on par with *Dharma* (religion) and *Artha* in terms of value (money). *Kama* specifically refers to achieving physical intimacy and healthy progeny, which are often essential for happiness in life and whose absence can severely impair one's quality of life.

Physical and mental vigor, as well as the sexual urge that comes from virility (Ca.Ci.2-4/45), are all factors in virility.^[1] To explain the physiology of sexual act, both physical and psychological components must be considered. According to the description given in Ayurvedic classics, ejaculation of semen is a natural accompaniment of erection and followed by sexual act, where erection is a necessary precursor to execute the sexual act resulting in ejaculation. (Ca.Ci.2-4/47^[2] and Su.Ni.10/19-22)^[3] *Samkalpa* (passionate attachment); *Chesta: Sparsa* (touch); *Nishpeedana* (specific stimulation/masturbation); *Śukrasravana* or *Shukrachyuti* (ejaculation).

OBJECTIVES

Through this study, the ED250 capsule is used to clinically test the efficacy of *Kuchla* (*Strychnos nuxvomica*) and *Brahmi* (*Bacopa monnieri*) in the management of *Klabiaya* or *Dhwajbhanga* or erectile dysfunction.

MATERIALS AND METHODS

All the patients were selected by keeping in view the symptomology of *Klaibya* (*Dhwajbhanga*) in

Access this article online

Quick Response Code



<https://doi.org/10.47070/ayushdhara.v8i5.804>

Published by Mahadev Publications (Regd.)
publication licensed under a Creative
Commons Attribution-NonCommercial-
ShareAlike 4.0 International (CC BY-NC-SA
4.0)

Ayurvedic text as well as criteria mention in modern text for erectile dysfunction. 30 clinically diagnosed patients of *Dhwajbhang* or erectile dysfunction from OPD of M.M.M.Govt.Ayurveda College Hospital, Motichohta Hospital, *Anusandhan Kendra* (Udaipur), Rajasthan (India) selected and registered in college hospital. I've chosen four main signs and symptoms for spot diagnosis in this work. The origins of even if a person has a great desire to perform sexual acts with a cherished, willing, and cooperative partner, he seems unable to coitus with her due to the lack of penis erection or penile rigidity.

- No penile erection in the morning.
- Do not use *Vajikar Dravyas* and have a history of excessive coitus.
- There is no sexual passion and no erection.
- PME (Project Management Expertise) (Pre mature ejaculation).

Inclusion Criteria

For this investigation, patients who met the following general and diagnostic criteria were chosen.

1. Patients with partial or complete erectile dysfunction reported with symptoms.
2. Patients between the ages of 21 and 65.
3. A patient with Type 2 diabetes or hyperlipidemia.
4. *Dhwajbhang* patients will be diagnosed by the specific scoring system introduced by Mehra BL *et al.* in the *Vajikarana* lab I.P.G.T. and R.A. with certain modifications was implemented for the first time.
5. Each mentioned a patient with IIEF-identified sexual dysfunction.

Exclusion Criteria

1. Patient who is not well diagnosed.
2. History of penile trauma, injury or surgery.
3. Congenital disorders.
4. Serious mental disorders.
5. History of chronic cardiovascular or neurological disorders.
6. Homosexual person

Criteria for Withdrawal

1. During the course of trial if any serious condition or any serious disease is found in patient.
2. Patients himself wants to withdraw from the clinical trial.

Criteria of Assessment Adopted for Present Study

The International Index of Erectile Function Questionnaire (IIEF) [4]

IIEF-15 questionnaire was adopted to rule out the sexual problems in the individual and for the assessment of the result of the dysfunctions found in

this. Some definitions of the words which were used in this questionnaire; sexual activity includes intercourse, caressing, foreplay and masturbation. Sexual intercourse is defined as sexual penetration of your partner sexual stimulation includes situation such as foreplay, erotic pictures etc. Ejaculation is the ejection of semen from the penis (or the feeling of this). Orgasm is the fulfilment or climax following sexual stimulation or intercourse. These questions ask about the effects that the erection problems have had on patient's sex life over the past 4 weeks.

The first five questions refer to erectile function

Q1. Over the last month, how often were you able to get an erection during sexual activity?

- 0- No sexual activity
- 5- Almost always or always
- 4- Most times (much more than half the time)
- 3- Sometimes (about half the time)
- 2- A few times (much less than half the time)
- 1- Almost never or never

Q2. Over the last month, when you had erections with sexual stimulation, how often were your erections hard enough for penetration?

- 0- No sexual activity
- 5- Almost always or always
- 4- Most times (much more than half the time)
- 3- Sometimes (about half the time)
- 2- A few times (much less than half the time)
- 1- Almost never or never

Q3. Over the last month, when you attempted intercourse, how often were you able to penetrate your partner?

- 0- No sexual activity
- 5- Almost always or always
- 4- Most times (much more than half the time)
- 3- Sometimes (about half the time)
- 2- A few times (much less than half the time)
- 1- Almost never or never

Q4. Over the last month, during sexual intercourse, how often were you able to maintain your erection after you had penetrated your partner?

- 0- No sexual activity
- 5- Almost always or always
- 4- Most times (much more than half the time)
- 3- Sometimes (about half the time)
- 2- A few times (much less than half the time)
- 1- Almost never or never

Q5. Over the last month, during sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?

- 0- No sexual activity
- 1- Extremely difficult
- 2- Very difficult
- 3- Difficult
- 4- Slightly difficult
- 5- Not difficult

The next three questions refer to satisfaction with intercourse

Q6. Over the last month, how many times have you attempted sexual intercourse?

- 0- No attempts
- 1- 1-2 times
- 2- 3-4 times
- 3- 5-6 times
- 4- 7-10 times
- 5- 11-20 times

Q7. Over the last month, when you attempted sexual intercourse how often was it satisfactory for you?

- 0- Did not attempt intercourse
- 5- Almost always or always
- 4- Most times (much more than half the time)
- 3- Sometimes (about half the time)
- 2- A few times (much less than half the time)
- 1- Almost never or never

Q8. Over the last month, how much have you enjoyed sexual intercourse?

- 0- No intercourse
- 5- Very highly enjoyable
- 4- Highly enjoyable
- 3- Fairly enjoyable
- 2- Not very enjoyable
- 1- No enjoyment

The next two questions refer to orgasmic function

Q9. Over the last month, when you had sexual stimulation or intercourse, how often did you ejaculate?

- 0- No sexual stimulation/intercourse
- 5- Almost always or always
- 4- Most times (much more than half the time)
- 3- Sometimes (about half the time)
- 2- A few times (much less than half the time)
- 1- Almost never or never

Q10. Over the last month, when you had sexual stimulation or intercourse, how often did you have the feeling of orgasm (with or without ejaculation)?

- 0- No sexual stimulation/intercourse
- 5- Almost always or always
- 4- Most times (much more than half the time)

- 3- Sometimes (about half the time)
- 2- A few times (much less than half the time)
- 1- Almost never or never

The next two questions ask about sexual desire. In this context, sexual desire is defined as a feeling that may include wanting to have a sexual experience (for example masturbation or sexual intercourse), thinking about having sex, or feeling frustrated due to lack of sex

Q11. Over the last month, how often have you felt sexual desire?

- 5- Almost always or always
- 4- Most times (much more than half the time)
- 3- Sometimes (about half the time)
- 2- A few times (much less than half the time)
- 1- Almost never or never

Q12. Over the last month, how would you rate your level of sexual desire?

- 5- Very high
- 4- High
- 3- Moderate
- 2- Low
- 1- Very low or not at all

The next two questions refer to overall sexual satisfaction

Q13. Over the last month, how satisfied have you been with your overall sex life?

- 5- Very satisfied
- 4- Moderately satisfied
- 3- About equally satisfied and dissatisfied
- 2- Moderately dissatisfied
- 1- Very dissatisfied

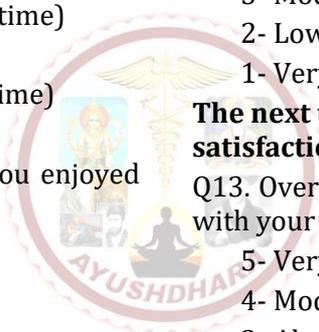
Q14. Over the last month, how satisfied have you been with your sexual relationship with your partner?

- 5- Very satisfied
- 4- Moderately satisfied
- 3- About equally satisfied and dissatisfied
- 2- Moderately dissatisfied
- 1- Very dissatisfied

The last question refers to erectile function

Q15. Over the last month, how do you rate your confidence that you can get and keep your erection?

- 5- Very high
- 4- High
- 3- Moderate
- 2- Low
- 1- Very low



Ayurvedic Criteria include developed by Vajikarana lab I.P.G.T. and R.A. with some modification [5]

Symptoms	Parameters	Grading
Harsh (Erection)	No erection or swelling without any methods	00
	Erection with artificial method	01
	Very slight swelling but unable to penetrate	02
	Some swelling, able to penetrate	03
	Erection with occasional failure	04
	Full swelling whenever desire	05
Rigidity	No rigidity at all	00
	Some stiffness but unable to penetrate	01
	Loss of stiffness, can penetrate but unable to maintain till last	02
	Some loss of stiffness, able to maintain till last	03
	Fully rigid to maintain erection to continue the sexual intercourse till last	04
<i>Sankalpa Pravan</i> (Sexual Desire)	No desire at all	00
	Lack of desire	01
	Desire in sex but no sexual act	02
	Desire only in demand of partner	03
	Self and partner normal desire	04
	Excess desire	05
<i>Vyavaysheelata</i> (Frequency of Coitus)	No intercourse	00
	1-2 coitus/week	01
	3-4 coitus/week	02
	>4 times in a week	03
<i>Shrama</i> (Post Act Exhaustion)	After every sexual act	00
	In 75% of the encounters	01
	In 50% of the encounters	02
	In 25% of the encounters	03
	Slight exhaustion occasionally	04
	No exhaustion at all	05
<i>Ratikriya</i> (Performance Activity)	Anxiety that hamper in almost all the counters	00
	Anxiety that hamper in 75% of the encounters	01
	Anxiety that hamper in 50 % of the encounters	02
	Anxiety that hamper in 25% of the encounters	03
	Slight anxiety, does not hamper sexual act	04
	No anxiety at all	05
<i>Veerya Skhalan</i> (Ejaculation)	Ejaculation on mere thoughts/sight or no ejaculation at all	00
	Ejaculation during foreplay	01
	Ejaculation before penetration	02
	Ejaculation during sexual intercourse < 30 s, with at least 1-5 pelvic thrusts	03
	Ejaculation during sexual intercourse < 60s, with at least 5-10 pelvic thrusts	04
	Ejaculation during sexual intercourse 60 s, with at least 10 or >10 pelvic thrusts	05
<i>Praharshan</i> (Orgasm)	No orgasm at all	00
	Lack of enjoyment in most of the occasions	01
	Enjoyment in 25% sexual intercourse by ejaculation inside the vagina	02
	Enjoyment in 50% sexual intercourse by ejaculation inside the vagina	03

	Enjoyment in 75% sexual intercourse by ejaculation inside the vagina	04
	Enjoyment in every sexual intercourse by ejaculation inside the vagina	05
Feeling After Sex	No satisfaction after every act	00
	Satisfaction in 25% act	01
	Satisfaction in 50% act	02
	Satisfaction in 75% act	03
	Satisfaction after every act	04
Feeling of Partner (After Sex)	No satisfaction after every act	00
	Satisfaction in 25% act	01
	Satisfaction in 50% act	02
	Satisfaction in 75% act	03
	Satisfaction after every act	04
Night Emissions	No night	00
	emission/week	01
	1-2/week	02
	3-4/week	03
	>4/week	04

Trial Drugs: ED250 (Hypothetical) contains the following drugs

These mentioned were taken in described proportion and the compound prepared in M.M.M. Govt. Ayu. College pharmacy.

Shodhan Process of Kuchla^[6]: Ancient literature prescribes more than one *Shodhana* process for detoxification of the *Strychnos nuxvomica*.

Nux-vomica seeds soaked in *Gomutra* (cow urine) for 7 nights; fresh *Gomutra* is to be replaced every night. Thereafter, it is removed and washed with hot water. Then seeds shall be further detoxified by *Swedana* (boiling with *Godugdha* (cow milk) in *Dola Yantra* for 3h). The seed coat and embryo are removed. The cotyledon roasted in cow ghee and powdered well. It claims that the detoxified seeds are highly potent and can be used safely. Analysis of phytochemical and physiochemical study performed in lab.

S. No.	Drug's Name	Botanical Name	Part	Ratio	Dosage
01.	Shodhit Kuchla Powder	<i>Strychnos nux-vomica</i>	Seed	1	125mg
02.	Brahmi Extract 20%	<i>Bacopa monnieri</i>	Panchang	1	125mg

Investigation Criteria

- Routine examinations performed in all the selected patients (to relate the effect of associated diseases only): HB%, CBC, Random blood sugar/fasting/pp/HbA1c test, Lipid profile and Sperm analysis.

Others are as per needed:

- Urine test
- Penile USG
- Blood Pressure
- Total testosterone

Study Type

Randomized control clinical trial.

The registered patients were grouped into two;

Group A

ED 250 capsule (Hypothetical) once a day (250mg) with milk HS.

Group B

Placebo group with milk HS or before 30 minutes to coitus.

Assessment Phase

Total 30 patients were registered under this groups, they were further divided into two groups among them one received CAP ED 250 and other received placebo treatment. Total 18 patients were registered in CAP. ED250 treated group out of them 15 had completed and 3 had discontinued the treatment while in placebo treated group. Total 18 patients were registered and 3 had discontinued the treatment and the results obtained on various parameters are as under. The effect of the treatment (results) was assessed regarding the clinical sign and symptoms (On the basis of grading and scoring system) and overall improvement.

Data analysis: All the Results are calculated by using Software: In Stat Graph Pad 3.

- For Nonparametric Data Wilcoxon matched-pairs signed ranks test is used, results calculated for all groups.
- For calculating the Inter group comparison, Mann Whitney Test.

Scoring Algorithm for IIEF 15

All items are scored in 5 domains as follows:

Domain	Items (questions)	Range	Score Max
Erectile Function	1, 2, 3, 4, 5, 15	0-5	30
Orgasmic Function	9, 10	0-5	10
Sexual Desire	11, 12	1-5	10
Intercourse Satisfaction	6, 7, 8	0-5	15
Overall Satisfaction	13, 14	1-5	10

OBSERVATION AND RESULTS

Table 1: Sexual dysfunctions including ED reported in 36 patients

Dysfunctions as per IIEF counting		Severe	Moderate	Mild to moderate	Mild
Erectile Function	No. of Patients	2	4	25	5
	%	5.55	11.11	69.44	13.88
Orgasmic Function	No. of Patients	1	6	16	13
	%	2.77	16.66	44.44	36.11
Sexual Desire	No. of Patients	0	6	21	9
	%	0	16.66	58.33	25
Intercourse Satisfaction	No. of Patients	1	6	17	12
	%	2.77	16.66	47.22	33.33
Overall Satisfaction	No. of Patients	0	3	26	7
	%	0	8.33	72.22	19.44

Table 2: Relation between age and incident of erectile dysfunction (ED)

Age group (year)		Severe ED	Moderate ED	Mild to Moderate ED	Mild ED
21-30	No. of Patients	1	3	6	NA
	%				
31-40	No. of Patients	1	NA	12	NA
	%				
41-50	No. of Patients	NA	1	7	2
	%				
51-60	No. of Patients	NA	NA	1	1
	%				
Above 60	No. of Patients	NA	NA	1	NA
	%				

Table 3: Status of the 36 pts of Dhwajbhanga or Erectile Dysfunction

Status	Group placebo	Group ED250	Total	Percentage
Completed	15	15	30	83.33
Drop outs	3	3	6	16.66
Total Registered	18	18	36	100

Table 4: Symptoms wise distribution reported in 30 patients of Dhwajbhanga or ED

Associated Sexual Complaints	No. of Patients			
	Group ED 250	Group Placebo	Total	Percentage
<i>Sankalp Pravana</i> (Lack of Sexual Desire)	06	04	10	33.33
<i>Vyavaysheelata</i> (Low Frequency of Coitus)	12	07	19	63.33
<i>Shrama</i> (Post Act Exhaustion)	12	12	24	80.00
Performance Anxiety	03	04	07	23.33
Pre mature Ejaculation	06	09	15	50.00
<i>Praharshan</i> (Low Orgasm)	10	10	20	66.66
Night Emissions Absent	05	06	11	36.66

Table 5: Erectile dysfunction reported in 30 patients of Dhwajbhanga or ED as per IIEF

Erectile function	No. of Patients			
	Group ED 250	Group Placebo	Total	Percentage
No dysfunction	00	00	00	00
Mild dysfunction	02	00	02	6.66
Mild to moderate dysfunction	10	13	23	76.67
Moderate dysfunction	02	01	03	10.00
Severe dysfunction	01	01	02	06.66

Table 6: Associated diseases reported in 30 patients of Dhwajbhanga or ED

Associated Diseases	No. of Patients			
	Group ED 250	Group Placebo	Total	Percentage
Diabetes Mellitus	03	01	04	13.33
Hypertension	03	02	05	16.66
Hyperlipidemia	04	01	05	16.66
<i>Sthaulya</i> (Obesity)	02	00	02	6.66
<i>Karshya</i> (Low BMI)	01	03	04	13.33
Psychological	05	06	11	36.66
Peripheral neuropathy	00	00	00	00.00
I.H.D.	00	00	00	00.00
P.V.D.	00	00	00	00.00

Table 7: Age wise distribution in 30 patients of Dhwajbhanga or ED

Age (in year)	No. of Patients			
	Group ED 250	Group Placebo	Total	Percentage
21 – 30	1	8	9	30
31 – 40	8	4	12	40
41 – 50	5	2	7	23.33
51- 60	1	1	2	6.66

Table 8: Nature of disease - progress in 30 patients of *Dhwajbhanga* or ED

Nature of Progress	No. of Patients			
	Group ED 250	Group Placebo	Total	Percentage
Progressive	11	13	24	80
Non-Progressive	04	02	06	20

Table 9: NPT (Nocturnal Penile Tumescence) wise distribution in 30 patients of *Dhwajbhanga* or ED

NPT	No. of Patients			
	Group ED 250	Group Placebo	Total	Percentage
Positive	10	12	22	73.33
Negative	03	02	05	16.66
Sometimes Positive	02	01	03	10.00

Table 10: Addiction wise distribution in 30 patients of *Dhwajbhanga* or ED

Addiction	No. of Patients			
	Group ED 250	Group Placebo	Total	Percentage
Tobacco chewing	00	02	02	6.66
Smoking	03	01	04	13.32
Alcohol and Smoking	05	05	10	33.3
Alcohol	00	05	05	16.65
Tea	00	01	01	3.33
Coffee	00	00	00	0
No addiction	07	06	13	43.29

Table 11: Patterns of mood in 30 patients of *Dhwajbhanga* or ED

Mood Patterns	No. of Patients			
	Group ED 250	Group Placebo	Total	Percentage
Normal	15	04	19	63.27
Elevated	00	00	00	0
Depressed	04	03	07	23.31
Anxious	06	07	13	43.29
Swinging	00	01	01	3.33

Table 12: Knowledge of sex in 30 patients of *Dhwajbhanga* or ED

Knowledge of sex	No. of Patients			
	Group ED 250	Group Placebo	Total	Percentage
Sufficient	06	07	13	43.33
Less	07	02	09	30.00
Poor	02	06	08	26.66

Table 13: Masturbation indulgence wise distribution in 30 patients of *Dhwajbhanga* or ED

Masturbation indulgence	No. of Patients			
	Group ED 250	Group Placebo	Total	Percentage
Masturbatory act before marriage				
Yes	15	15	30	100
No	00	00	00	00
At present				
Yes	03	05	08	26.66
No	12	10	22	73.33

Table 14: Prakriti wise distribution in 30 patients of Dhwajbhanga or ED

Prakriti		No. of Patients				
		Group ED 250	Group Placebo	Total	Percentage	
Sharira	V	01	00	01	3.33	
	p	00	00	00	0	
	K	00	00	00	0	
	VP	04	10	14	46.62	
	KP	04	02	06	20	
	VK	06	03	09	30	
	<i>Tridoshaja</i>	00	00	00	0	
	Manasa	SR	04	02	06	20
		RT	00	00	00	0
		ST	00	00	00	0
<i>Rajas</i>		06	08	14	46.62	
<i>Tamas</i>		05	05	10	33.3	

Table 15: Showing Effect of Therapy on Ayurvedic Subjective Parameters. (Wilcoxon Matched Pairs Single Ranked Test)

Parameter	Groups	N	Mean ±SEM			% Diff.	S.D. mean diff	'p'	Result
			BT	AT	Diff.				
Harsh (Penile Erection)	Group ED250	15	3.133 ± 0.236	3.600 ± 0.235	0.467 ± 0.001	14.89	0.005	0.068	NS
	Group Placebo	15	3.067 ± 0.206	3.667 ± 0.159	0.600 ± 0.047	19.57	0.182	0.045	S
Penile Rigidity	Group ED250	15	1.733 ± 0.118	2.333 ± 0.126	0.600 ± 0.008	34.62	±.030	<0.001	HS
	Group Placebo	15	1.733 ± 0.118	2.200 ± 0.107	0.467 ± 0.011	26.92	±.044	0.014	S
Sankalpa Pravan (Sexual Desire)	Group ED250	15	2.733 ± 0.384	3.800 ± 0.175	1.067 ± 0.209	39.02	±.081	<0.001	HS
	Group Placebo	15	3.200 ± 0.341	3.533 ± 0.291	0.333 ± 0.050	10.42	±.195	0.173	NS
Veerya Skhalan (Early Ejaculation)	Group ED250	15	2.333 ± 0.252	3.800 ± 0.107	1.467 ± 0.145	62.86	0.562	<0.001	HS
	Group Placebo	15	2.267 ± 0.181	3.400 ± 0.130	1.133 ± 0.051	49.97	0.196	<0.001	HS
Praharshan (Orgasm)	Group ED250	15	1.867 ± 0.236	3.067 ± 0.153	1.200 ± 0.080	64.29	0.322	<0.001	HS
	Group Placebo	15	1.667 ± 0.270	3.200 ± 0.145	1.533 ± 0.125	92.00	0.486	<0.001	HS
Ratikriya (Performance Anxiety)	Group ED250	15	1.867 ± 0.236	3.067 ± 0.153	1.200 ± 0.083	64.29	0.322	<0.001	HS
	Group Placebo	15	1.667 ± 0.270	3.200 ± 0.145	1.533 ± 0.125	92.00	0.486	<0.001	HS
Shrama (Post Act Exhaustion)	Group ED250	15	1.733 ± 0.345	2.533 ± 0.215	0.800 ± 0.129	46.15	0.501	0.005	S
	Group Placebo	15	2.000 ± 0.293	2.533 ± 0.215	0.533 ± 0.078	26.67	1.134	0.088	NS
Vyavaysheelata (Frequency of	Group ED250	15	1.133 ± 0.192	1.667 ± 0.187	0.534 ± 0.005	47.06	0.019	<0.001	HS

Coitus)	Group Placebo	15	1.533 ± 0.236	1.933 ± 0.153	0.400 ± 0.078	26.09	0.322	0.028	S
	Group ED250	15	1.600 ± 0.273	2.533 ± 0.165	0.933 ± 0.108	58.33	0.416	<0.001	HS
Self-Satisfaction	Group Placebo	15	1.067 ± 0.267	2.400 ± 0.163	1.333 ± 0.104	125.00	0.400	<0.001	HS
	Group ED250	15	1.867 ± 0.274	2.867 ± 0.133	1.000 ± 0.141	53.57	0.544	<0.001	HS
Partner's Satisfaction	Group Placebo	15	1.333 ± 0.347	2.600 ± 0.163	1.267 ± 0.184	95.00	0.713	<0.001	S
	Group ED250	15	1.733 ± 0.153	2.067 ± 0.118	0.333 ± 0.035	19.23	0.136	0.019	S
Night Emission	Group Placebo	15	1.800 ± 0.200	2.267 ± 0.118	0.467 ± 0.082	25.93	0.317	<0.001	HS

Table 16: Showing Effect of Therapy on IIEF Questionnaire Parameters (Wilcoxon Matched Pairs Single Ranked Test)

Parameter	Groups	N	Mean ±SEM			% Diff.	S.D. mean diff	'p'	Result
			BT	AT	Diff.				
Erectile Function	Group ED250	15	14.533 ± 1.064	19.067 ± 0.483	4.533 ± 0.581	31.19	2.251	<0.001	HS
	Group Placebo	15	15.467 ± 0.888	20.133 ± 0.336	4.667 ± 0.552	30.17	2.139	<0.001	HS
Orgasm Function	Group ED250	15	6.000 ± 0.447	7.000 ± 0.293	1.000 ± 0.154	16.67	0.598	0.016	S
	Group Placebo	15	6.533 ± 0.446	7.200 ± 0.223	0.667 ± 0.223	10.30	0.865	0.019	S
Sexual Desire Function	Group ED250	15	6.067 ± 0.452	6.667 ± 0.333	0.600 ± 0.119	9.89	0.460	0.023	S
	Group Placebo	15	6.800 ± 0.480	7.533 ± 0.291	0.733 ± 0.189	10.78	0.734	0.022	S
Intercourse Satisfaction	Group ED250	15	7.800 ± 0.678	10.200 ± 0.368	2.400 ± 0.310	30.77	1.200	<0.001	HS
	Group Placebo	15	8.600 ± 0.505	10.800 ± 0.262	2.200 ± 0.243	25.58	0.942	<0.001	HS
Overall Satisfaction	Group ED250	15	5.800 ± 0.327	6.867 ± 0.192	1.067 ± 0.135	18.39	0.522	<0.001	HS
	Group Placebo	15	5.667 ± 0.211	6.867 ± 0.192	1.200 ± 0.019	21.18	0.073	<0.001	HS

Intergroup Comparison

To access the efficacy of two therapies intergroup comparison was done. As the variables are nonparametric **Mann Whitney U test** was used for statistical analysis. The results are as follows:

Table 17: Intergroup Comparison in IIEF 15 Parameters (Mann Whitney U test)

Parameter	n	IIEF Parameters (Mann Whitney U test)			P value	Significantly different (P < 0.05)	P value summary
		Mean Diff ±SEM ED 250 Group	Mean Diff ±SEM Placebo Group	U value			
Erectile Function	15	4.533 ± 0.581	4.667 ± 0.552	98.50	0.5675	NO	NS

Orgasm Function	15	1.000 ± 0.154	0.667 ± 0.223	101	0.6095	NO	NS
Sexual Desire Function	15	0.600 ± 0.119	0.733 ± 0.189	108	0.8666	NO	NS
Intercourse Satisfaction	15	2.400 ± 0.310	2.200 ± 0.243	92	0.3711	NO	NS
Overall Satisfaction	15	1.067 ± 0.135	1.200 ± 0.019	101	0.7232	NO	NS

Complete Effect on Therapy

Subjective parameters on overall effect of therapy in 30 patients

Relief in complete remission in both group is 13.33% because 2 patients were belonging to psychogenic ED and 2 were with *Shukravegavdharan*; markedly improved (75-99%) in group ED 250 6.66; moderately improved (50-74%) in Group ED250 13.33% and Group Placebo 26.66; mildly improved (25-49%) in group ED 250 40% and in Group Placebo 26.66%; Unchanged or less effect (<25%) in Group ED250 and Group Placebo 33.33%. Data is showing clearly that the group of ED250 is showing a better result besides of placebo group.

IEF15 parameters on overall effect of therapy in 30 patients

Statistically Relief in complete remission in both group is 6.66%; markedly improved (75-99%) in both group nil; moderately improved (50-74%) in Group ED250 6.66% and Group Placebo 6.66%; mildly improved (25-49%) in group ED250 6.66% and in Group Placebo 6.66%; unchanged or less effect (<25%) in Group ED250 and Group Placebo 80%.

DISCUSSION

Before developing any theory, *Upanayana* (discussion) is the first phase, according to classical research technique to *Nigamana* (conclusion). Discussion is a method of self-reflection. It provides a framework for the conclusion. Despite extensive classical research and experimentation in numerous forms, a theory is only accepted after adequate observational reasoning (*Tarka*). The discussion reveals the findings and observations. As a result, discussion is an essential component of any scientific study. In the present study surprisingly the age group of 51 to 65 satisfies with their sex life. While the young age group (21-40 years) is going to convert in ED patients and dissatisfy with their sexual life. The main causative factors affecting are; sedentary life style, stressful life, consuming alcohol and cigarettes, using porn sites and using tight garments. As the ayurvedic perspective; Better lifestyle, anti-depressant Drugs, *Pranayam*, *Yoga* and *Asans*, *Vrashya* (Aphrodisiac) *Aahar-Vihar-Aushadh* can give a supreme sex life. In the study we work on it and find the significantly high results in Placebo group, which proved the Ayurvedic

treatment is more successful in Psychogenic ED from the ancient time to since present time. With NPT negative, the progressive nature signifies organic pathology, whereas the non-progressive nature denotes psychological disorders. NPT is usually positive in psychogenic ED and negative in organic disorders (associated with other diseases), however it is negative in certain patients with anxiety and sadness.

Role of Associated Diseases and ED

Some patients reported lack of rigidity after penetration associated with early ejaculation and found it difficult to differentiate. Hyperlipidemia, or increased weight (*Meda dhatu vikrati*), is a cause of decreased blood flow in arteries, as well as post-act tiredness, performance anxiety, and low semen levels in some people. Acharya *Charaka* and *Sushruta* both mentioned the *Sapta Dhatu nirman* sequence (*Rasad raktam tato masa shukrad*) and told i.e., *Dhatudushti* in a specific *dhatu* produce the lower of the sequence in next one (*Pratiloma Kshaya*). As many patients were from labor and lower middle class having low calorie diet, produce a *Rasa dhatu vikrati*, they reported low body weight, lower the quality of semen and misconcepts about sex life. In diabetic subjects general weakness is found as a symptom in many cases and *Charaka* has also mentioned *Daurbalya* as complication of *Prameha*. The link between diabetes and ED is well-known - Diabetes is one of the more common physical causes of ED. It is associated with reduced quality of life among those affected. Diabetic impotence has a complicated aetiology, with neurogenic, vascularogenic, and dysfunctional local neuro effect contributing to the ED pathology. On the contrary present study finds out that the patient who is taking regularly medication related to maintain diabetes does not showing any severe or moderate type of ED. *Ayurveda* is also says; there is no direct reference is available in Ayurvedic classics to say that *Madhumeha* leads to *Klaibya*. *Charaka* has also mention *Daurbalya* as a complication of *Madhumeha*. On the contrary present study finds out that the patient who is taking regularly medication related to maintain diabetes does not showing any severe or moderate type of ED. There are some patients finds who have severe or moderate type oligospermia and

they feel fatigue, depression and low sexual desire, Early ejaculation was triggered in some cases by the nervousness associated with the performance due to a lack of rigidity. Lack of desire further deteriorates the erectile process. In the placebo group result showing higher because of a number of young age are included which were mostly affected by psychogenic factors like *Krodha* (anger), *Chinta* (worry), *Shoka* (grief) and *Udvega* (anxiety). Most of them had PME. The anxious and depressed mood due to *Chinta*, *Shoka*, *Bhaya* etc causes disturbance in sexual desire and Vigor in its chronic state. Among the all patient; some young patients are affected with moderate or mild to moderate type of ED; were feel very depressed and anxious before going to perform a sex. They were unable to maintain an erection during coitus. Finally, after several sessions of counselling, had pleasurable coitus with an erection that lasted to the end, and so on. Due to a lack of sufficient sex education, many perversions and prejudices may arise. According to the findings of the current study, premarital affairs will undoubtedly have an impact on sexual life after marriage. Failed and terrible experiences during foreplay or coitus, in particular, create emotional trauma, and the person develops anxiety about his performance and sadness as a result of repeated failure encounters, hampering the marital sexual life later on. That could be why the people who admitted to having extramarital affairs failed the study.

Role of Habits in ED

The patients who reported masturbation in this study may be doing just because they have an elevated sexual desire that isn't being met by their partners. Hormonal variations can be destructive to sexual, physical, and mental health. As a result, there is still debate among males over whether masturbating is beneficial or bad. Some patients in the current study live apart from their partners due to their jobs; some of them do not masturbate and acquire a moderate type of ED, while others who masturbate develop a mild type of ED Because of their early ejaculation habits. Smoking and alcohol play a significant impact in the development of severe ED. The role of vegetarian and non-vegetarian diets does not appear to impact ED circumstances; nonetheless, there is a misunderstanding that non-vegetarian diets improve vigour.

Role of Prakriti in ED

According to Ayurveda, *Vataja* & *Pittaja* *Prakriti* individuals are prone for *Alpashukrata* (Ca.Vi. 8/98). In the present study i.e., maximum no. of patients (~47%) were linked with *Vata-Pattik prakriti*.

Effect of Therapy on as per IIEF Parameters (Inter group Study)

Effect of Placebo and Test Drug on Erectile Function

This function belongs to IIEF 15 question no 1 to 5 and 15; Both the group showing near equally result; the reason behind this may be because of medicine effect and counselling help them to increase the confidence level to keep erection threw the psychogenic establishment and relief in PME, increase the chances of penetration with maintain erection to completion intercourse.

Effect of placebo and test drug on Orgasm Function

Q9 & Q10 refer to orgasmic function. The ED 250 group showed a significant improvement in erectile dysfunction relief, improved ejaculation quality, and increased erection timing and pelvic thrust counting.

Effect of placebo and test drug on Sexual Desire Function

Q11 and Q12 are questions about sexual desire and compare the effects of a placebo and a test drug cap ED250. In this context, sexual desire is defined as an emotion that includes the desire to have a sexual experience (such as masturbation or sexual intercourse), thinking about having sex, or feeling irritated because of a lack of intimacy. Both groups exhibit no change since their levels of sexual desire are increasing at the same time.

Effect of placebo and test drug on Intercourse Satisfaction

Q6 to Q8 refer to the effect of compared study on intercourse satisfaction; this includes sexual intercourse enjoyment and attempted sexual intercourse. The directly connected intercourse enjoyment improved when erectile function was improved. Group ED250 showing a much higher results than placebo.

Effect of placebo and test drug on Overall Satisfaction

Because the majority of patients in the placebo group were psychogenic and young, the results were highly significant.

Probable Mode of Action of the Therapy

Brahmi or *Bacopa monnieri* shows *karma* from *Prabhav*; maintain the psychogenic factors by their antidepressant, anti-stress and cardiovascular properties. Due to its *Tikta Rasa* (bitter taste), both drugs used as bitter stomachic and tonic. Both drugs show central nervous system stimulant increases the blood flow. Both drugs are notifying effect on the nervous system i.e., ED 250 showing much result not only the persons affected by psychological ED but also those is affected by co morbid conditions. *Brahmi* and *Kuchla* both drugs have *Tikta rasa* nature. *Tikta rasa*

suppress *Pitta* and *Kapha*. *Pitta dosha* is a key factor of disturbed sleep and quality of semen. Alleviated *Pitta* can cause of anger and depression. *Acharya charaka* mentioned *Brahmi* in the *Prajasthapna* and *Garbhsthapna Mahakashaya*; may be because *Brahmi* maintain the mood and anxiety of *Garbhini* and safe with obstacles during pregnancy. Same side in a man during a stress or anxiety, he cannot perform during intercourse. *Brahmi* reduce the stress and anxiety by their properties. Several researches have revealed that *Brahmi* has antidepressant, anxiolytic, anti-diabetic, nervine tonic, sedative and less hypnotic properties. *Kuchla* or *Nuxvomica* showing their result because it is a strong nervine stimulant (motor)^[7] and as a circulatory stimulant increase the blood flow in arteries immediately, which is support to rigidity of penis. After taking a proper history and a wonderful counselling of couple with ED250 contents give a satisfactory result in Organic and Psychogenic both types of ED patients.

CONCLUSION

A much number of patients in ED250 group were affected with associated disease like Diabetes Mellitus, Hyperlipidemia, Obesity, Oligospermia etc. They were strictly followed the exercise, maintain medication and diet chart in the duration of trial. The combined effect of therapy with Cap. ED 250 significantly reduces *Kalibya* in participants by improving Penile Rigidity, *Veerya Chyuti* (lowering PME), *Vyavaysheelata* (frequency of coitus), and providing relief from psychogenic symptoms such as *Sankalpa Pravan* (sexual desire), *Ratikriya* (performance anxiety), *Praharshan* (orgasm), self and partner's satisfaction. Thus, it is a new addition in the list of Ayurvedic drugs related to ED and PME conditions. On the basis of all results obtained in the clinical study it can be concluded clearly that particularly result is better by Cap. ED250, but statistically both the group showing equal result in both groups i.e., the final result of the overall therapy is non-significant. It includes aspects such as proper

counselling, lifestyle changes, diet modification and pharmacological effects. Organic and psychological factors influence penile erection and rigidity all the way to the end, resulting in low sexual confidence. To make a choice, more research and a large sample size survey are required.

REFERENCES

1. Agnivesh. Caraka and Drdhabala. Charaka Samhita, Elaborated Vidyotini Hindi Commentary, Kashinatha Sastri Part 1 (Sutra Sthan), Varanasi; Chaukhamba Bharati Academy, Reprint 2016; p. 7
2. Agnivesh. Caraka and Drdhabala. Charaka Samhita, Vaidya H.C.Kushwaha Edited with Ayurveda Deepika Hindi Commentary; Vol II (Chikitsa sthana), Varanasi; Chaukhamba Orientalia, 2012; p. 66.
3. Dr. Anant Ram Sharma. Sushruta Samhita, Susruta Vimarsini Hindi commentary, Vol I (Nidanasthana); Varanasi; Chaukhamba Surbharati Prakashana, p.536.
4. Rosen R, Riley A, Wagner G, et al. The International Index of Erectile Function (IIEF): A multidimensional scale for assessment of erectile dysfunction. Urology, 1997, 49: 822-830.
5. Santosh Bhattad: A comparative study of the role of Vajikarana drugs administered orally and by basti in management of klaibya with reference to erectile dysfunction. M.D. Ayu thesis, March 2002, Jamnagar.
6. Rabinarayan Acharya; Shodhana: An Ayurvedic detoxification Technique and Its Impact on Certain Medicinal Plants A Concept Of Visa [homepage on the Internet], Chapter [Cited 2014 January], Available from <https://www.Researchgate.Net/Publication/282317743>
7. C.P. Khare (Ed.) Indian Medicinal Plants An Illustrated Dictionary springer Springer-Verlag Berlin/ Heidelberg © Springer Science+ Business Media, LLC

Cite this article as:

Deepak Verma, Ashwini Kumar Sharma, Megha Shukla. A Randomised Clinical Control Study to Evaluate the Efficacy of Shodhita Kuchla Powder (Purified Strychnos Nux-Vomica L.) and Brahmi Extract (Bacopa Monnieri L. Pennell) on Klaibya (Dhwajbhang) w.s.r. to Erectile Dysfunction. AYUSHDHARA, 2021;8(5):3511-3523.

<https://doi.org/10.47070/ayushdhara.v8i5.804>

Source of support: Nil, Conflict of interest: None Declared

*Address for correspondence

Dr. Deepak Verma

Assistant Professor,
PG Department of
Dravyaguna Vigyan,
Dayanand Ayurved College,
Jalandhar (Punjab).

Email:

dr.deepakverma3@gmail.com