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An open label single arm clinical study on the effectiveness of *Akarakarabha Vati* in the management of *Klaibya* (Erectile Dysfunction)

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ABSTRACT

Background: *Klaibya* (Erectile Dysfunction) is one of the common sexual disorders that affects physical and psychosocial health and may significantly impact the quality of life of sufferers and their partners. Sexual health and function are important determinants of quality of life. Although lifestyle modifications and psychotherapy are considered as the first-line of treatment in Erectile Dysfunction (ED), men presenting with such complaints expect the *Ayurveda* physician to help them with measures and medication that can have an improved result. *Akarakarabaha* is a potent drug mentioned in classical textbooks which is having the *Shukrasthambaka* (inhibition of delayed ejaculation), *Balya* (strength promoting activity), *Vrishya* (aphrodisiac), *Vajikara* properties and it's having pharmacological activities like antioxidants, aphrodisiac, immunomodulatory effect, antidepressant, anti-diabetic, and effect on testosterone. **Methods:** Among 11 subjects, 10 of them completed the course of treatment. They were administered with *Akarakarabha Vati* 500 mg twice a day with milk as *Anupana* after food for 30 days and 15 days after cessation of medicine. For statistical analysis subjective parameters were assessed with Cochran Q test followed by McNemar test also Friedman's test followed by Wilcoxon sign rank test, and objective parameters were assessed by repeated measure ANOVA followed by Paired t-test. **Results:** There was statistically significant improvement in the *Klaibya Samanya Lakshana* and IIEF (International Index of Erectile function) score. **Conclusion:** *Akarakarabaha Vati* is effective in the management of *Klaibya* (Erectile Dysfunction).

Key words: *Ayurveda, Klaibya, Erectile dysfunction, Akarakarabaha, Vajikarana*

INTRODUCTION

Vajikarana is a branch of *Ashtanga Ayurveda* that deals with reproduction, potency, and healthy offspring. In this discipline, infertility and sexual dysfunctions are diagnosed and treated in depth. *Klaibya* is a condition

where even the man desires sexual intercourse and the partner is cooperative, he cannot perform the sexual act because of the absence of erection due to loss of rigidity. Erectile dysfunction (ED) is a common medical problem affecting approximately 15% of men each year and it's estimated to affect more than 150 million men. Its incidence has been projected to increase significantly to over 320 million by the year 2025.^[1] It is widely noticed in society, owing to a less generally reported sense of inadequacy. According to a survey conducted by the Massachusetts Male Aging Study (MMAS), 52 percent of males between the ages of 40 and 70 had some form of erectile dysfunction.^[2] Sexual well-being is a crucial aspect of overall health. The couple's sexual concord conceals the couple's attainment of conjugal existence. In order to keep marital peace and happiness, healthy sexual functioning is essential. Sexual dysfunction has an

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impact on couple's psychology, conduct, and relationships, which in turn impacts the quality and harmony of marital life, affecting the family and society. In the long run, it could lead to a variety of psychosomatic diseases in both couples. It gives a medium for expressing love, which serves as the foundation for all kinds of creative endeavours. The lack of which stifles the marital connection, leading to dissatisfaction and, in some cases divorce, as well as inefficiencies in executing ordinary tasks. Male Sexual Dysfunction encompasses coital performance and sexual intercourse issues in men. The achievement of a proper erection with sufficient stiffness for penetrative intercourse is the most important phase of sexual response, and its absence leads to failure and disappointment.

In *Ayurveda*, *Klaibya* is a condition where even the man desires sexual intercourse and the partner is cooperative, he cannot perform the sexual act because of the absence of erection due to loss of rigidity and even if a man attempts sexual act he exhibits breathlessness and perspiration. It is including of *Bahudoshavastha* (multifactorial vitiation of ailments) and *Shukrakshaya* (Hypospermia) as a whole, in specific *Mano Dosha* (containments of mind) and *Shukravaha Sroto* (seminal pathway) *Dusti*.

Despite the fact that lifestyle changes and patient education^[3] are the first-line treatments for erectile dysfunction (ED), men who present with such symptoms expect the physician to help them with medications that can have improved results. Better ED therapies are thus constantly a prime research priority. Here we have intended to assess the effectiveness of *Akarakarabaha Vati* in the management of *Klaibya* (Erectile Dysfunction). To fulfil this aim we have selected this study.

MATERIALS AND METHODS

Method of collection of data

11 Patient were screened and selected based on the *Klaibya Samanaya Lakshana*^[4] and based on IIEF score with specified inclusion like, Subjects with Minimum 3 months history of erectile dysfunction, aged between

25 to 60 years having Fairly good glycemic condition (DMT2) and exclusion criteria like, K/C/O essential hypertension and cardiac, hepatic, renal disorders, significant anatomical penile deformity, and history of prostatectomy or penile implant.

Table 1: Demographic and observational data in 11 *Klaibya* subjects on the bases of *Samanya Lakshana*.

Lakshana	Present	Absent
<i>Linga Shaitily</i>	11(100%)	0
<i>Mogha Sankalpa Chesta</i>	11(100%)	0
<i>Mlana Shishnata</i>	11(100%)	0
<i>Swasatha</i>	5(45.5%)	6(54.5%)
<i>Swinna Gatrata</i>	8(72.7%)	3(27.3%)

International index of erectile function (IIEF) contains 15 questionnaire which are about the effects the individual erection problems have had on their sex life over the last four weeks. Categorised under 5 main domain. Sexual activity includes intercourse, caressing, foreplay & 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.

Table 2. Demographic and observational data in 11 *Klaibya* subjects based on IIEF.

Q1. How often were you able to get erection during sexual activity?			
Score	Erectile function	Frequency	Percentage
0	No sexual activity	0	0
1	Almost never or never	2	18.2
2	A few times (less than half time)	8	72.7

3	Sometimes (about half the time)	0	0
4	Most times (more than half the time)	1	9.1
5	Almost always	0	0
Q2. When you had erections with sexual stimulation, how often were your erections hard enough for penetration?			
Score	Erectile function	Frequency	Percentage
0	No sexual activity	0	0
1	Almost never or never	1	9.1
2	A few times (less than half time)	8	72.7
3	Sometimes (about half the time)	2	18.2
4	Most times (more than half the time)	0	0
5	Almost always	0	0
Q3. When you attempted intercourse, how often were you able to penetrate (enter) your partner?			
Score	Erectile function	Frequency	Percentage
0	Did not attempt intercourse	0	0
1	Almost never or never	6	54.5
2	A few times (less than half time)	4	36.4
3	Sometimes (about half the time)	1	9.1
4	Most times (more than half the time)	0	0
5	Almost always	0	0
Q4. During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?			
Score	Erectile function	Frequency	Percentage

0	Did not attempt intercourse	0	0
1	Almost never or never	8	72.7
2	A few times (less than half time)	3	27.3
3	Sometimes (about half the time)	0	0
4	Most times (more than half the time)	0	0
5	Almost always	0	0
Q5. During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?			
Score	Erectile function	Frequency	Percentage
0	Did not attempt intercourse	0	0
1	Extremely difficult	7	63.6
2	Very difficult	3	27.3
3	Difficult	1	9.1
4	Slightly difficult	0	0
5	Not difficult	0	0
Q15. How do you rate your confidence that you could get and keep an erection?			
Score	Erectile function	Frequency	Percentage
1	Very low	0	0
2	Low	11	100.0
3	Moderate	0	0
4	High	0	0
5	Very high	0	0
Q9. When you had sexual stimulation or intercourse, how often did you ejaculate?			
Score	Orgasmic function	Frequency	Percentage

0	No sexual stimulation or intercourse	0	0
1	Almost never or never	0	0
2	A few times	0	0
3	Sometimes (about half the time)	8	72.7
4	Most times (more than half the time)	1	9.1
5	Almost always	2	18.2
Q10. When you had sexual stimulation or intercourse, how often did you have the feeling of orgasm or climax?			
Score	Orgasmic function	Frequency	Percentage
1	Almost never or never	0	0
2	A few times	0	0
3	Sometimes	7	63.6
4	Most times	2	18.2
5	Almost always	2	18.2
Q11. How often have you felt sexual desire?			
Score	Sexual Desire	Frequency	Percentage
1	Almost never or never	0	0
2	A few times	0	0
3	Sometimes	3	27.3
4	Most times	7	63.6
5	Almost always	1	9.1
Q12 how would you rate your level of sexual desire?			
Score	sexual desire	Frequency	Percentage
1	Very low or none at all	0	0
2	Low	0	0
3	Moderate	3	27.3

4	High	8	72.7
5	Very high	0	0
Q6. How many times have you attempted sexual intercourse?			
Score	Intercourse satisfaction	Frequency	Percentage
0	No attempts	0	0
1	One to two attempts	4	36.4
2	Three to four attempts	5	45.5
3	Five to six attempts	1	9.1
4	Seven to ten attempts	1	9.1
5	Eleven or more attempts	0	0
Q7. When you attempted sexual intercourse, how often was it satisfactory for you?			
Score	Intercourse satisfaction	Frequency	Percentage
0	Did not attempt intercourse	0	0
1	Almost never or never	8	72.7
2	A few times (less than half time)	3	27.3
3	Sometimes	0	0
4	Most times	0	0
5	Almost always	0	0
Q8. How much have you enjoyed sexual intercourse?			
Score	Intercourse satisfaction	Frequency	Percentage
0	No intercourse	0	0
1	No enjoyment at all	7	63.6
2	Not very enjoyable	4	36.4
3	Fairly enjoyable	0	0
4	Highly enjoyable	0	0
5	Very highly enjoyable	0	0

Q13. How satisfied have you been with your overall sex life?			
Score	Overall satisfaction	Frequency	Percentage
1	Very dissatisfied	8	72.7
2	Moderately dissatisfied	3	27.3
3	Equally satisfied & dissatisfied	0	0
4	Moderately satisfied	0	0
5	Very satisfied	0	0

Q14. How satisfied have you been with your sexual relationship with your partner?			
Score	Overall satisfaction	Frequency	Percentage
1	Very dissatisfied	8	72.7
2	Moderately dissatisfied	1	9.1
3	Equally satisfied & dissatisfied	2	18.2
4	Moderately satisfied	0	0
5	Very satisfied	0	0

Table 3: Distribution of 11 subjects of Klaibya based on Performance Anxiety

Performance Anxiety	Count	%
Present	10	90.9
Absent	1	9.1

OBSERVATION AND RESULTS

Table 4: Effect of therapy on Erection.

Parameter	N	Mean	Greenhouse - geisser			Greenhouse - geisser Error df	Remarks
			df	F value	p value		
Erection BT total score	10	10.100	1.362	40.980	<.05	12.258	S
Erection 15 th day		14.800					

total score						
Erection 30 th day total score		17.800				
Erection 45 th day total score		16.300				

(I) Erection	(J) Erection	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval for Difference		Remarks
					Lower Bound	Upper Bound	
1	2	-4.700	.472	<.0125	5.769	-3.630	S
2	3	-3.000	.258	<.0125	-3.584	-2.415	S
3	4	1.500	1.024	>.0125	-3.584	-2.415	NS

Table 5: Effect of therapy on Intercourse satisfaction.

Parameter	N	Mean	Greenhouse - geisser			Greenhouse - geisser Error df	Remarks
			df	F value	P value		
Intercourse satisfaction BT total score	10	5.200	1.000	17.063	<.05	18.930	S

Intercourse satisfaction 15 th day total score	7.200					
Intercourse satisfaction 30 th day total score	8.000					
Intercourse satisfaction 45 th day total score	6.600					

Table 6: Effect of therapy on Sexual Desire.

Parameter	N	Mean	Greenhouse - geisser			Greenhouse - geisser Error df	Remarks
			df	F value	P value		
Sexual desire BT total score	10	7.500	1.000	2.250	>.05	9.000	NS
Sexual desire 15 th day total score		7.700					
Sexual desire 30 th day total score		7.700					
Sexual desire 45 th day total score		7.700					

(I) Intercourse Satisfaction	(J) Intercourse Satisfaction	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval for Difference		Remarks
					Lower Bound	Upper Bound	
1	2	-2.000	0.365	<.0125	-2.826	-1.173	S
2	3	-0.800	0.326	>.0125	-1.538	0.061	NS
3	4	1.400	0.339	<.0125	0.6310	2.1689	S

Table 7: Effect of therapy on Orgasmic Function.

Parameter	N	Mean	Greenhouse - geisser			Greenhouse - geisser Error df	Remarks
			df	F value	P value		
Orgasmic function BT total score	10	6.900	1.000	2.250	>.05	9.000	NS
Orgasmic function 15 th day total score		7.100					

Orgasmic function 30 th day total score	6.900					
Orgasmic function 45 th day total score	6.900					

Table 8: Effect of therapy on Overall Satisfaction

(I) Overall Satisfaction	(J) Overall Satisfaction	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval for Difference		Remarks
					Lower Bound	Upper Bound	
1	2	-1.700	0.213	<.0125	-2.182	-1.217	S
2	3	-1.600	0.163	<.0125	-1.964	-1.230	S
3	4	-0.600	0.221	>.0125	-1.100	-0.998	NS

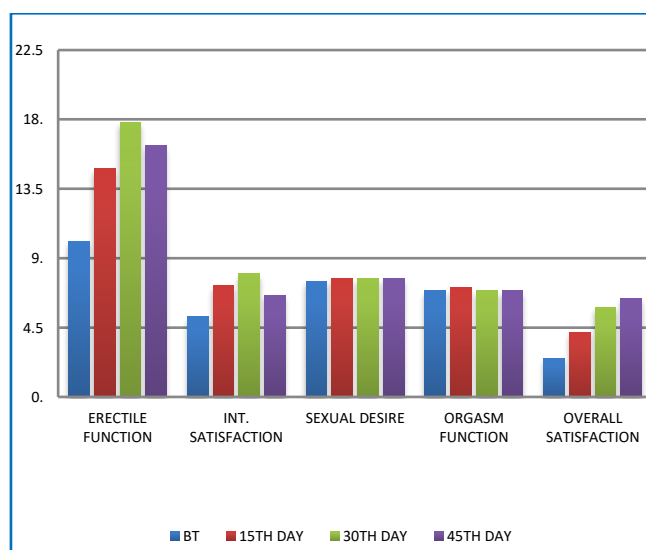
Parameter	N	Mean	Greenhouse – geisser			Greenhouse – geisser Error df	Remarks
			df	F value	P value		
Overall satisfaction BT total score	10	2.500	2.137	105.0	<.05	19.236	S

Overall satisfaction 15 th day total score	4.200					
Overall satisfaction 30 th day total score	5.800					
Overall satisfaction 45 th day total score	6.400					

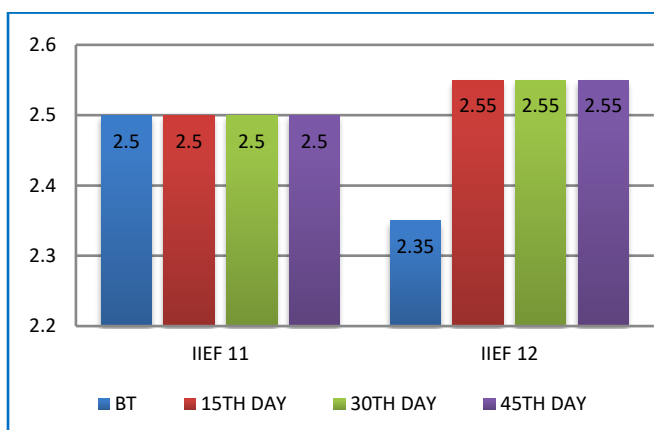
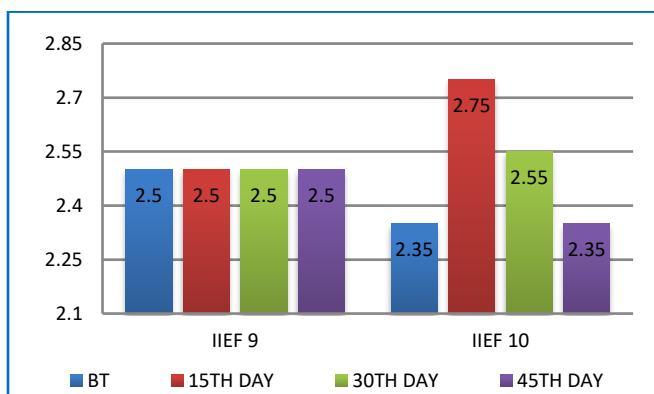
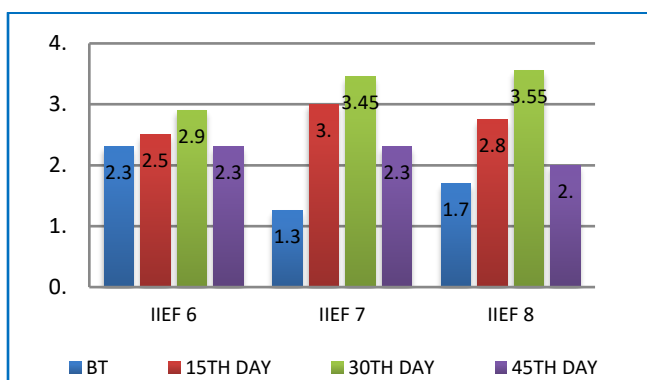
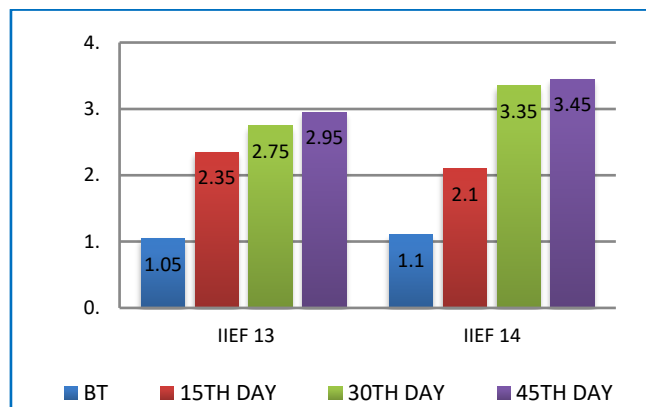
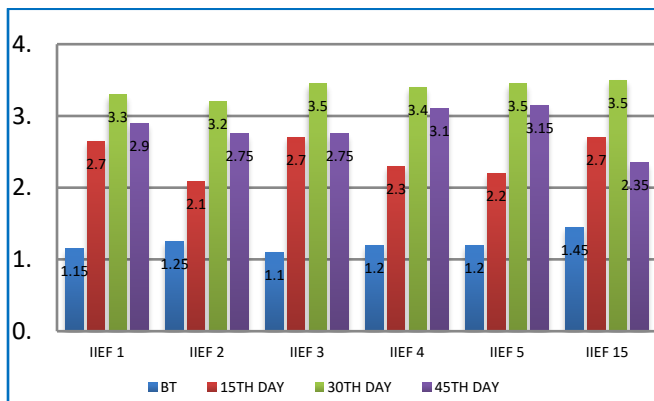
Table 9: Effect of therapy on Performance Anxiety

Performance Anxiety	Present	Absent	N	P	Remarks
BT	10	0	10	<0.05	S
15 th Day	2	8			
30 th Day	0	10			
45 th Day	0	10			

Bar diagrams 1: Demographic and Observational data in 11 subjects.



Bar diagrams 2: Effect of Therapy on IIEF Scale.



DISCUSSION

In the present study, 20 subjects were screened, 11 were registered of which 10 have completed the course of treatment. The subjects were asked for follow up on 15th day, 30th day and 45th day. Sexual parameters were assessed before treatment and during each follow up on the basis of International Index of Erectile function. The results obtained on various parameters were statistically analyzed and presented in the forms of Tables. For statistical analysis subjective parameters were assessed with Cochran Q test followed by McNemar test and objective parameters were assessed by Friedman's test followed by Wilcoxon sign rank test and Repeated Measure Anova followed by Paired t-test.

Probable effect of Akarakarabha Vati on Klaibya

Akarakarabha possesses the Vrishya, Shukrasthambaka, Balya, Vajikara properties as mentioned in Priya Nighantu^[5] and Brihat Nighantu Ratnakara.^[6] Akarakarabha (*Anacyclus pyrenthrum*) is most widely growing species of the family Asteraceae. The plant having several pharmacological actions such as aphrodisiac, antidiabetic, immunostimulant, inhibitory effects, antidepressant activity, anticonvulsant activity, memory-enhancing activity, antimicrobial activity, antioxidant, local anaesthetic effect, insecticidal effect, interactions with testosterone, interaction with libido, and its interaction with testicles.^[7] Akarakarabha having *Katu Rasa Pradhana* and *Teekshna Guna* which may does *Srotoshodhana* and it may clear the *Srotas* which further increase the blood flow there by improves the erectile function.^[8]

As *Akarakarabha* is having the properties like *Balya* and *Vatahara*, it may help in the *Klaibya Lakshana* like, *Linga Shaitilya* (flaccidity of penis) and *Mlanashishnata* (loss of penile strength due to loss of rigidity) there by improves the *Moghasankalpa Chesta* (futile sexual act). It possesses *Shukrasthambana* property which helps in *Shukragatavata* and may help in the *Klaibya*.

Effect of Akarakarabha Vati on erectile function

There was a statistically significant change in the Erectile function and intercourse satisfaction from BT to 30th day (on intervention) and it shown non-significant after 45th day follow up without intervention. But overall significant improvement seen from BT to 45th day. As a result of *Apana Vatadushti*, the penis could become *Shitila* and *Mlana*, resulting in erectile dysfunction. *Akarakarabhaha's* qualities such as *Balya* and *Vatahara*, it aids in the treatment of *Klaibya Lakshanas* such as *Linga Shaitilya* (penile laccidity) and *Mlana Shishnata* (penile stiffness loss) and so improves the *Moghasankalpa Chesta* (futile sexual act) there by it improves the erectile function. It has *Shukra Sthambana*, which helps with *Shukragatavata* and also aid with *Klaibya*. *Akarakarabha* contains *Katu Rasa* (pungent) and *Teekshnaguna* (penetrating properties), which may perform *Sroto Shodhana* (purification of channels), increasing blood flow and so improving erectile function.

As decreased antioxidant defenses is prevalent in ED and play major roles in reducing vascular nitrous oxide. *Akarakarabha* contains a natural source of antioxidants due to the presence of DPPH (di-phenyl picrylhydrazyl-hydrate) in the drug which helps to generate NO in vascular level improve blood circulation. Thereby improves the erectile function.^[9]

Effect of Akarakarabha Vati on sexual desire & orgasm

There was a statistically significant change in the Sexual desire and orgasm from BT to 30th day (on intervention) and it shown non-significant after 45th day follow up without intervention. Subjects were having proper Sexual desire and orgasmic function which further no change has been observed.

Effect of Akarakarabha Vati on intercourse satisfaction

There was a statistically significant change in the intercourse satisfaction from BT to 30th day (on intervention) and it shown non-significant after 45th day follow-up without intervention. But overall significant improvement seen from BT to 45th day. The penis may become *Shitila* (flaccid) and *Mlana* (loss of rigidity) as a result of *Apana Vatadushti*, resulting in erectile dysfunction. *Akarakarabha* possesses traits like *Balya* and *Vatahara*, and it can help with *Klaibya Lakshanas* like *Linga Shaitilya* (penile laccidity) and *Mlana Shishnata* (penile stiffness loss), as well as improving the *Moghasankalpa Chesta* (futile sexual act) and so improving erectile function. Intercourse satisfaction will improve as erectile function improves.

Effect of Akarakarabha Vati on overall satisfaction

There was a statistically significant change in the Overall satisfaction from BT to 30th day (on intervention) and it shown non-significant after 45th day follow up without intervention. But overall significant improvement seen from BT to 45th day. The overall satisfaction will improve once the erectile function, intercourse satisfaction, and sexual desire have improved.

CONCLUSION

The fundamental prerequisite for a proper sexual intercourse with a willing partner is a proper erection. Any sexual dissatisfaction leads to a significant negative attitude among couples toward one another, resulting in major family issues. Sexual disorders are becoming one of the leading reasons of family conflict and divorce. Ayurvedic research is aiming for a comprehensive revalidation of current elements using modern methods. An in-depth analysis and cautious appraisal are required to achieve that objective. In this study, administration of *Akarakarabhaha Vati* with milk as *Anupana* for the period of 30 days and 15 days after cessation of medicine had shown statistically significant improvement in the *Klaibya Lakshana* and in IIEF score on medication (i.e., BT- 30th Day). There was no significant change observed on cessation of

medicine (i.e., 30-45th Day). But overall, from BT to 45th day it was found to be significant. Hence *Akarakarabha Vati* of 500 mg twice a day after food with milk as *Anupana* for 30 days on intervention and after 15 days after cessation of intervention is effective in the management of *Klaibya*.

REFERENCES

1. Abolfo touch MA, Al-Helali NS. Effect of erectile dysfunction on quality of life. *Eastern Mediterranean Health Journal*, 2001, 7(3):510-518.
2. Feldman HA, Goldstein I, Hatzichristou DG, Krane RJ, McKinlay JB. Impotence and its medical and psychosocial correlates: Results of the Massachusetts Male Aging Study. *J Urol* 1994; 151:54-61.
3. Kasper, Braunwald, Fauci, Hauser, Longo, Jameson. Harrison's principles of internal medicine. 16 th ed. CD ROM. New York: McGraw-Hill Medical publishing division; 2005. Page no.272-273
4. Vaidya Harishandra Sinha Kushavaha. Charaka Samhita volume 2. Varanasi; Chaukamba Orientalia; reprint-2018 pg 822
5. P V Sharma, Priya Nighantu 2nd ed. 1995, 30/52, Pg. 84, Chaukhambha surabharati prakashan, Varanasi, Pages 275.
6. Golakvasi lala Shaligramaji VAishya, Brihat Nighantu Ratnakara 7-8th volume. ed.1997, pg.116-117, Khemaraj Shreekrishnadas Prakashan, Pages 935.
7. Khaleem Ahmad, Review on akarakarabha (Anacyclus pyrethrum); A unique single drug. *The journal of pharmacology* 2020;9(6):423-428
8. Vaidya Harishandra Sinha Kushavaha. Charaka Samhita volume 1. reprint- 2018, 26/43 pg.386 Varanasi; chaukamba orientalia; pg 962
9. Manouze H, Bouchatta O, Gadhi AC, Bennis M, Sokar Z, Ba-M'hamed S. Anti-inflammatory, Antinociceptive, and antioxidant activities of methanol and aqueous extracts of *Anacyclus pyrethrum* roots. *Frontiers in pharmacology*. 2017;8:598

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