



Research Article

CLINICAL STUDY TO EVALUATE THE EFFICACY OF *YAPANA BASTI* AND *VANARI GUTIKA* IN THE MANAGEMENT OF *KLAIBYA W.S.R.* TO ERECTILE DYSFUNCTION

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ABSTRACT

Successful sexual act is one of the most basic needs for the production of the future generations. Successful sexual act is not possible, if a person is suffering from the *Klaibya*. *Acharya* have mentioned different causes of the *Klaibya*, and *Malanashishinta* is one among these. *Malanashishinta* can be compared with the erectile dysfunction on the basis of symptoms.

The *Sthiradipanchamooladi Yapana Basti* (960ml/day for 16days), which is mentioned in the *Caraka Samhita* for *Vajikarana* by *Caraka* and *Vanari Gutika* (5gm twice daily was given P.O. with milk as *Anupana* for 30 days) mentioned by *Bhavaparkasha* in *Vajikarana* chapter are used in this study. One of the basic aims of this thesis is to evaluate, whether the drugs administered through *Basti* have any benefit over the drugs administered orally, particularly in reference to the administration of *Vajikarana* drugs for the treatment. Total 30 patients were selected from the OPD & IPD in the P.G.Department of *Panchakarma* at National Institute of Ayurveda Jaipur, Rajasthan. The patients were randomly divided into three groups and named as Group A, Group B and Group C, with 10 patients in each group. Highly significant result was found in overall effect the subjective criteria in the group of A, B and group C with 55.55%, 34.78% and 94.44% respectively. In the semen analysis highly significant result was found in group-c with 42.34 % (semen volume), 15.97 % (Sperm count) and in Immotile sperm 45.01% respectively.

KEYWORDS: *Kalaiya Sthiradipanchamooladi Yapana Basti, Vanari Gutika.*

INTRODUCTION

The Ayurveda is a science that deals with the human life. The first priority of *Ayurveda* is the prevention of disease and maintaining the health of a healthy individual^[1]. So, a man should follow such a dietary and daily regime, which will maintain his good health and prevent any illness in future^[2]. *Ayurveda* defines an ideal man as one who has got a healthy body, mind and *Indriya*, and leads such a life which is congenial to his personal development and conducive to social happiness. *Acharya Vagbhatta* has described the tripod of life as *Aahara, Nidra, and Abrahamcharya*. By the mention of *Abrahmcharya*, the *Acharya* gives a clear cut importance to sexual functions in human life.

The *Veda* divided human life into four stages i.e., *Brahmacharya, Grahstha, Vanprastha, and Sanyasa Asharama*. Through these stages a human being achieves *Dharma, Artha, Kama*, and finally *Moksha*, which is the ultimate goal of human life. *Acharya Susruta* has written a separate chapter, "*Shukrashonita Shudhi Adhyaya*", in which he has given complete description of "*Shudha Shukra, Shudha Shonita*", causes of deformities, and complete management. The aim of the chapter seems to be the production of *Shudha Shukra, Shudh Shonita*, so that, healthy human progeny is produced. *Acharya Caraka* has also mentioned in detail, "*Shudha Shukra, Shudha Shonita*", treatment of their diseases. *Caraka* has written a separate chapter on *Vajikarna*, and mentions that by following the rules and regulations of *Vajikarna* one can achieve healthy progeny. By achieving good progeny one achieves *Dharma, Artha, Preeti* and *Yasha*^[3]. Good progeny

benefits a person even in *Vanprastha* and *Sanyasa Ashram*. Successful sexual act is one of the most basic needs for the production of the future generations. Successful sexual act is not possible, if a person is suffering from the *Klaibya*. *Acharya* have mentioned different causes of the *Klaibya*, and *Malanashishinta* is one among these. *Malanashishinta* can be compared with the erectile dysfunction on the basis of symptoms. Due to the *Klaibya* a person is not able to produce offspring's. When a person is not able to complete his family, he is labelled with a social stigma. This becomes a reason for his physical, mental and social disturbance.

WHO defines the sexual dysfunction as "the various ways in which an individual is unable to participate in a sexual relationship as he or she would wish". The male sexual dysfunction includes all sorts of disturbances of coital performance and sexual congress in male. Male sexual dysfunction or "impotence" can be defined as a "man's inability to attain or maintain an erection of sufficient strength to perform the act of intercourse".

Oral pharmacotherapy represents the first line option for most of the patients with erectile dysfunction. Sildenafil and Apomorphine are presently used for erectile dysfunction in modern medicine. Patients who do not respond to oral pharmacotherapy or who cannot use it are good candidates for intracavernosal and intraurethral therapy. Alprostadil is the most widely used drug both for injection therapy and for the intraurethral route. It is estimated that currently 25–30 million men worldwide taking PDE5 inhibitors, and an additional 50 million or

more who are potential candidates for treatment. Now it is clear, that there are so many adverse effects of PDE5 inhibitors and no satisfactory result even after long time use. Nowadays, a famous medicine for erectile dysfunction is sildenafil, but it has negative side effects for cardiovascular system. Although, there are many drugs available for the treatment of the erectile dysfunction in allopathy but they have many serious adverse effects and are very costly.

Due to these reasons, the *Ayurvediya* system of medicine must play its role for the management of erectile dysfunction without lethal side effects. So, the aim of the study is to manage the erectile dysfunction by using chief, easily available and safe *Ayurvediya* medicines. The *Sthiradipanchamooladi Yapana Basti* which is mentioned in the *Caraka Samhita* for *Vajikarana* by *Caraka* and *Vanari Gutika* mentioned by *Bhavaparkasha* in *Vajikarana* chapter are used in this study. One of the basic aims of this thesis is to evaluate, whether the drugs administered through *Basti* have any benefit over the drugs administered orally, particularly in reference to the administration of *Vajikarana* drugs for the treatment.

Aims and Objectives

The present research trial has been undertaken with the following aims and objectives.

1. To conceptualize and evaluate the approach of *Ayurvediya* management in the *Klaibya* w.s.r. to erectile dysfunction.
2. To study the efficacy of the *Vanari Gutika* and the *Sthiradipanchamula Yapana Basti* in the management of the *Klaibya*.
3. To compare the efficacy of *Vanari Gutika* and the *Sthiradipanchamula Yapana Basti* on the *Klaibya*, when administrated separately and when given in the combination.

Materials and Methods

The following material and method were adopted for conducting the clinical trials.

Selection of Cases

Total 30 patients were selected from the OPD & IPD in the P.G.Department of Panchakarma at National Institute of Ayurveda Jaipur, Rajasthan.

Inclusion Criteria

- Adult male patients who were married and were b/w the age of 21 to 60 years.
- Patients having signs and symptoms of the *Klaibya* according to *Ayurveda* and Modern texts.

Exclusion Criteria

- Disorder in sexual organs e.g. hypospadias, epispadias etc.
- Unmarried Patients.
- Patients with diseases like severe Hypertension, Diabetes mellitus, IHD, COPD, Liver cirrhosis etc.
- Patients with sexually transmitted diseases.
- Erectile dysfunction due to nerve damage e.g. Accidental injury like spinal cord injury.
- Erectile dysfunction due to surgical cause e.g. surgery of colon, prostate, urinary bladder, rectum etc.

Study design and Grouping

This study was an open label, randomized, comparative, interventional study using pre-test and post-test design. After inclusion, the patients were randomly divided into three groups and named as Group A, Group B and Group C, with 10 patients in each group.

Selection of Drugs: In the present study, *Yapana Basti* was selected for one group. The *Vanari Gutika* was selected for the second group, and in third group both *Vanari Gutika* and *Yapana Basti* were administered simultaneously.

Groupings

Group-A: In this group *Sthiradipanchamoola Yapana Basti* was given approx. 960ml/day for 16days.

Group-B: In this group "*Vanari Gutika*" 5gm twice daily was given P.O. with milk as *Anupana* for 30 days.

Group-C: In this group, *Sthiradipanchamoola Yapana Basti* was given for 16 days, and "*Vanari Gutika*" as 5gm twice daily P.O. with milk as *Anupana* for 30 days.

Criteria for Assessment: Both subjective & objective parameters were employed for assessment of the impact of the treatment.

Subjective parameters: - The following signs and symptoms of *Klaibya* were assessed before and after the course of therapy.

1. *Mlanashishnata*^[4]

Clinical Interpretation of *Mlanashishnata*

Assessment of signs and symptoms was done pre and post trial on severity grading scale developed by Dr. Srinivas sharma et.al.

0	1	2	3	4	5
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- 0- No erection at all
- 1- Erection but not Sustained
- 2- Sustained Erection
- 3- Erection but not enough for penetration
- 4- Erection Enough for penetration
- 5- Successful intercourse

2. Efficacy Assessment of Parameters of Selected Drugs.

A) International Index of Erectile Function 15 items (IIEF-15)

These questions were asked about the effects that the erection problems have had on patient's sex life over the past 4 weeks:

Questionnaire:

Q.1. How often was you able to get an erection during sexual activity?

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

Q.2. When you had erections with sexual stimulation, how often were your erections hard enough for penetration?

0-No sexual activity

1-Almost never or never

2-A few times (less than half the time)

3-Sometimes (about half the time)

4-Most times (more than half the time)

5-Almost always or always

Q.3. When you attempted intercourse, how often were you able to penetrate

(Enter) your partner?

0-Did not attempt intercourse

1-Almost never or never

2-A few times (less than half the time)

3-Sometimes (about half the time)

4-Most times (more than half the time)

5-Almost always or always

Q.4. During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?

0-Did not attempt intercourse

1-Almost never or never

2-A few times (less than half the time)

3-Sometimes (about half the time)

4-Most times (more than half the time)

5-Almost always or always

Q.5. During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?

1-Did not attempt intercourse

2-Extremely difficult

3-Very difficult

4-Difficult

5-Slightly difficult

6-Not difficult

Q.15. How do you rate your confidence that you could get and keep an erection?

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

Scoring Algorithm for IIEF: All items are scored in 5 domains as follows:

Items Domain	(questions)	Range	Max Score
Erectile Function	1, 2, 3, 4, 5, 15	0-5	30

Clinical Interpretation of IIEF 5

Erectile function total scores can be interpreted as follows:

0-6 - Severe dysfunction.

7-12 - Moderate dysfunctions

13-18 - Mild to moderate dysfunction

19-24 - Mild dysfunctions

25-30 - No dysfunction

Objective parameters (semen analysis)

The analysis was carried out to assess the effect of the therapy before and after the treatment in the patients.

Statistical Analysis

In Stat Graph Pad 3 software was used & for non-parametric Data Wilcoxon matched-pairs signed ranks test was used while for Parametric Data Paired 't' Test was used and the results were calculated in each group. For calculating the Inter group comparison, KRUSKALWALLIS & ANOVA Test was used and results calculated.

- Insignificant: $P > 0.05$,
- Significant: $P < 0.05$
- Highly significant: $P < 0.01$, $P < 0.001$, $P < 0.0001$

Results

All the 30 subjects registered under all the three groups completed the course of the treatment for 30 days and follow up for 60 days. The effect of the therapy on different parameters like International Index of Erectile Function (IIEF) scoring, *Mlanashishnata* were assessed after the complete course of the treatment and follow up. The results obtained, before and after the treatments were analyzed by using Software: In Stat Graph Pad 3.

A) Effect of The therapy on the subjective parameter

1. Effect of the therapy on IIEF Q: 1

In **Group A, Group B and Group C** a relief of 92.31%, 91.66% and 90% was noted respectively, which is statistically significant ($p < 0.05$) in all the three groups.

2. Effect of the therapy on IIEF Q: 2

In **Group A, Group B and Group C** a relief of 80%, 76.92% and 93.75% was noted respectively, which is statistically significant ($p < 0.05$) in all the three groups.

3. Effect of the therapy on IIEF Q: 3

In **Group A, Group B and Group C** a relief of 52.94%, 56.25% and 94.11% was noted respectively, which is statistically significant ($p < 0.05$) in all the three groups.

4. Effect of the therapy on IIEF Q: 4

In **Group A, Group B and Group C** a relief of 75%, 73.33% and 91.66% was noted respectively, which is statistically significant ($p < 0.05$) in all the three groups.

5. Effect of the therapy on IIEF Q: 5

In **Group A, Group B and Group C** a relief of 42.85%, 36% and 93.75% was noted respectively, which is statistically significant ($p < 0.05$) in all the three groups.

6. Effect of the therapy on IIEF Q: 15

In **Group A, Group B and Group C** a relief of 55.55%, 34.78% and 94.44% was noted respectively, which is statistically significant ($p < 0.05$) in all the three groups.

7. Effect of the therapy on *Mlanashishnata*

In **Group A, Group B and Group C** a relief of 55%, 45% and 92.85% was noted respectively, which is statistically significant ($p < 0.05$) in all the three groups.

B) Effect of the therapy on the objective parameter

1. Effect of the treatment on Semen volume

In **Group A, Group B and Group C** an improvement of 35.75%, 28.76% and 42.34% was noted respectively, which is statistically significant ($P < 0.05$), significant ($p < 0.05$) and highly significant ($P < 0.0001$) respectively in the three groups.

2. Effect of the treatment on Semen pH

In **Group A, Group B and Group C** an improvement of 01.61%, 0.39% and 4.80% was noted respectively, which is statistically significant ($p < 0.05$), non-Significant ($P > 0.05$) and significant ($p < 0.05$) respectively in the three groups.

3. Effect of the treatment on sperm count

In **Group A, Group B and Group C** an improvement of 12.30%, 8.14% and 15.97 % was noted respectively, which is statistically significant ($P < 0.05$), significant ($p < 0.05$) and highly significant ($P < 0.0001$) respectively in the three groups.

4. Effect of the treatment on Rapid Linear Progression of sperm

In **Group A, Group B and Group C** an improvement of 26.17%, 19.31% and 30.88% was noted respectively, which is statistically highly significant ($P < 0.0001$), highly significant ($P < 0.0001$) and highly significant ($P < 0.0001$) respectively in the three groups.

5. Effect of the treatment on Sulggish Linear Progression of sperm:

In **Group A, Group B and Group C** an improvement of 18.14%, 15.85% and 19.22% was noted respectively, which is statistically highly significant ($P < 0.0001$), highly significant ($P < 0.0001$) and highly significant ($P < 0.0001$) respectively in the three groups.

6. Effect of the treatment on Non Progression of sperm:

In **Group A, Group B and Group C** an improvement of 20.58%, 20.70% and 34.19% was noted respectively, which is statistically significant ($P < 0.05$), significant ($p < 0.05$) and highly significant ($P < 0.0001$) respectively in the three groups.

7. Effect of the treatment on immotile sperm:

In **Group A, Group B and Group C** an improvement of 40.90%, 38.44% and 45.01% was noted respectively, which is statistically highly significant ($P < 0.0001$), highly significant ($P < 0.0001$) and highly significant ($P < 0.0001$) respectively in the three groups.

Table 4: Inter group comparison between Group A, Group B and Group C

Variables	Group A	Group B	Group C	P Value	Remark
IIEF Q:1	1.2	1.1	0.9	0.0465	S
IIEF Q:2	1.2	1	1.5	0.6485	NS
IIEF Q:3	0.9	0.9	1.6	0.0654	NS
IIEF Q:4	1.2	1.1	1.1	0.321	NS
IIEF Q:5	0.9	0.9	1.5	0.047	S
IIEF Q:15	1	0.8	1.7	0.422	NS
Mlanashishnata	1.1	0.9	1.3	0.8764	NS

(HS: Highly Significant S: Significant NS: Non Significant)

Graph 1: Inter group comparison between Group A, Group B and Group C

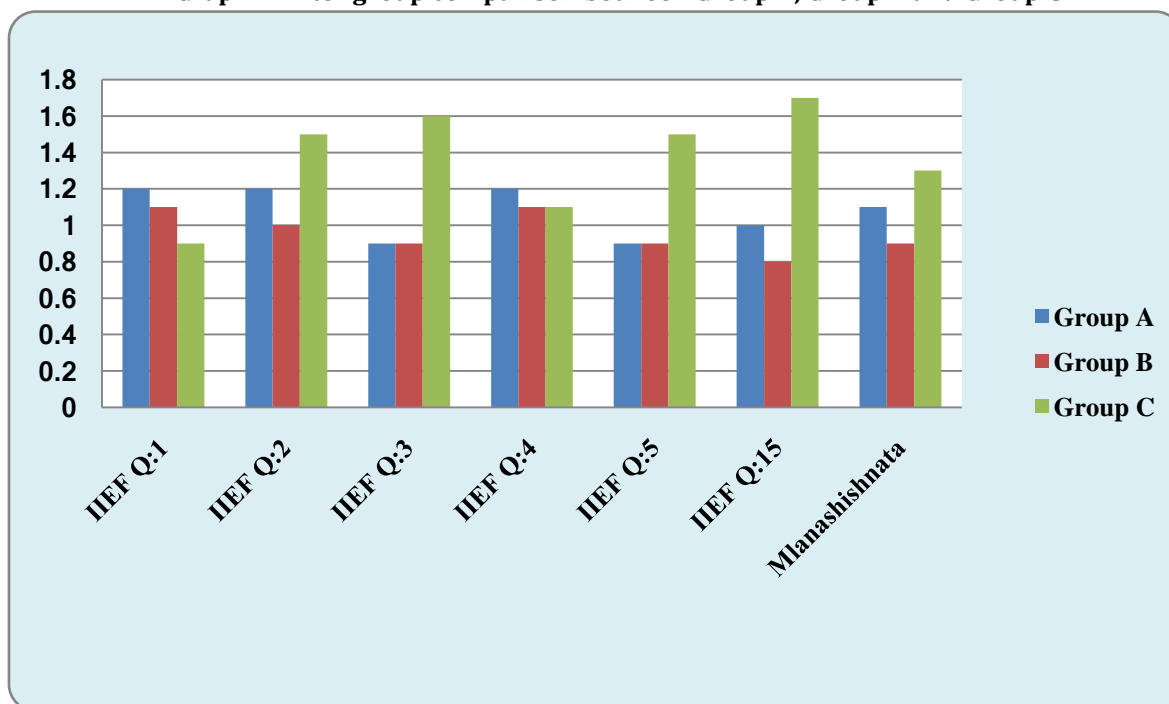
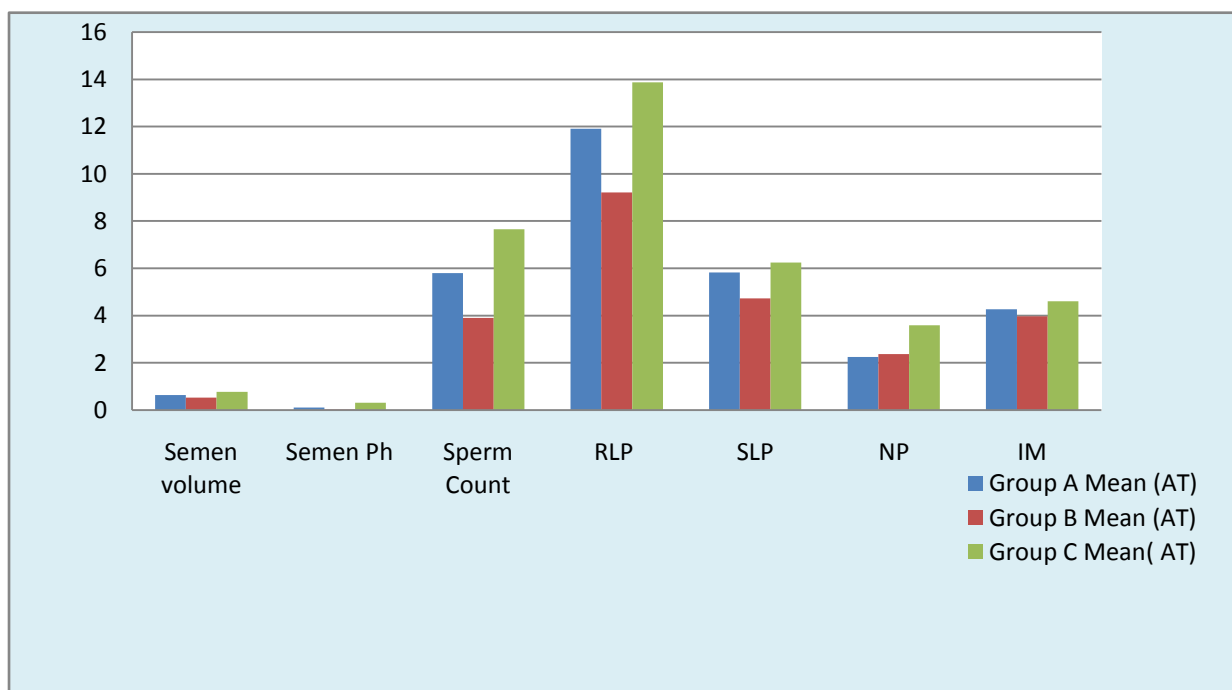


Table 8: Inter group comparison between Group A, Group B and Group C for objective parameters (semen analysis)

Variables	Group A Mean (AT)	Group B Mean (AT)	Group C Mean(AT)	P value	Remark
Semen volume	0.64	0.53	0.77	0.1717	NS
Semen pH	0.105	0.025	0.309	0.0039	S
Sperm Count	5.796	3.906	7.65	0.1241	NS
RLP	11.91	9.21	13.87	0.1045	NS
SLP	5.819	4.724	6.245	0.4366	NS
NP	2.247	2.367	3.59	0.5133	NS
IM	4.27	3.972	4.61	0.4511	NS

(RLP- Rapid linear progressive, SLP- Sluggish linear progress, NP- non progressive, IM-Immotile sperm)

Graph 2: Inter group comparison between Group A, Group B and Group C for objective parameters (semen analysis)



DISCUSSION

Ayurvediya Acharya Caraka has placed the *Kama* as one among the cardinal factors of *Purushartha*. This shows the importance they have attributed to *Kama*. The other three factors include *Dharma* (virtuous action), *Artha* (wealth), and *Moksha* (salvation). The *Kama* means *Sukha* it is attained by the virtuous actions and by making good use of the wealth. Even though the *Kama* is having a broad meaning, in the present study it is used to mention the sexual desire. It comprises many other factors including the normal functioning of behavior, social, psychological and physiological factors. In a sexual act, even though male plays leading role, female too have to perform her role properly. As sexual union is not an individual entity, the partners have equal responsibility in the successful completion of the intercourse; they are assigned with duties to have pleasure and satisfaction. Any dissatisfaction between the partners in successful sex causes a strong unpleasant attitude towards each other and is the root-cause of many family conflicts, divorces and

even suicides.

Successful sexual-life is the result of the balance of *Sharirik* and *Mansik Dosha*. *Vata* is the prime reason for vitiation of other *Dosha*. *Yapan Basti* balances the *Vata*, and is *Balya*, *Shukramasvardhak*, and *Sarvaroga-prashamana*. *Shukra* has a dual function, not only producing the sperm but also *Ojas*, the finest product of digestion. *Ojas* creates *vigor*, bliss, lightness, stamina, immunity, luster in the skin, and sparkle in the eyes, and clarity of mind. *Ojas* is vital to the health and happiness of everyone. Anyone who wants mental clarity, immunity, and spiritual well-being will find these recommendations useful, because it enhances the *Shukra dhatu* and thus enhance *Ojas*." These properties result in good health, good quality of *Shukra Dhatu*, and hence prove beneficial in *Klaihya*.

Bavaparkasha claims that *Vanari Gutika* is most superior medicine among all the *Vajikarana Ausadha* for *Linga shaithilaya*. *Kapikacchu* is the main ingredient

having *Madhura Rasa*, *Madhura Vipaka* and *Guru Guna*. These properties make it *Dhatu Pushtikaraka*^[5]. *Kapikachu* is well known for its aphrodisiac action. In addition, it is having mood elevating property too. *Kapikachu* is a good source of dopamine^[6]. More specific to sexual function, it is likely that dopamine triggers penile erection. The other constituents i.e., *Dugdha*, *Sharkra*, *Madhu*, *Gogrih* are mainly *Balya* and contribute towards good health. By, these qualities *Vanari Gutika* proves very beneficial in the management of the *Klaibya*.

Probable Mode of Action of the Therapy

A) Discussion on *Sthiradipanchamoola yapana Basti*

Vata is a very important *Dosha* to be managed during the treatment of any disease, as *Acharya* told that other *Dosha* are handicapped without *Vata Dosha*^[7], & *Basti* is the prime therapy in the management of *Vata Dosha*, & is called as *Ardhachikitsa* in any sort of disease, as mentioned in *Carak Siddhithana*^[8]. Also, *Sushruta* in *Cikitsasthana* chapter 35 mentioned not only in *Vata Dosha*, but *Pittaja*, *Kaphaja*, *Raktaja*, *Sansarga*, *Sannipatika* conditions can be benefited by *Basti*. *Acharya Sushruta* compared *Doshnirharana* potential of *Basti* with the Sun. He told that *Basti* has the potential to excrete morbid *Dosha* from all the parts of the body even though it is *Pakvashayastha*, in the same way that the Sun has potential to suck all the *Rasa* in *Prithvi*, even though it resides in *Aakash*^[9].

Discussion on *Vanari Gutika*

Although a number of medicines are described in classical literatures of *Ayurveda*, we have selected one recipe called *Vanari Gutika* from *Bavaparkasha*. *Kapikacchu* is having *Dhatu Pushtikaraka*. *Kapikachu* is well known for its aphrodisiac action. In addition, *Kapikachu* is a good source of dopamine. More specific to sexual function, it is likely that dopamine can trigger penile erection, by acting on neurons located in the paraventricular nucleus of the hypothalamus, and perhaps on the pro-erectile sacral parasympathetic nucleus within the spinal cord. So, central dopamine is a key neurotransmitter in the control of sexual function^[10]. *Dugdha* is well known aphrodisiac and life stabilizer drug. Being *Rasayana*, *Dugdha* improves the quality of *Dhatu* produced and also brings the *Dushti* of *Dhatu* (*Dusya*) to a normal state. *Ghritha* with its *Sheeta Virya* and *Rasayana* properties helps in improving all the *Dhatu*. *Ghritha* is proved to be beneficial for aphrodisiac purpose and delays the ageing. *Sharkra* is *Madhura in Rasa*, *Balya*, *Daha Nashak* and *Shukrala*. So it is useful in increasing the stamina and therefore helps in the management of the *Klaibya*.

CONCLUSION

The conclusion is the final outcome of any scientific study. The *Klaibya* is a disease which affects ones normal life to a great extent by making cracks in the relation of partners and there by disturbing the peace of mind of both the partners. The *Klaibya* is one of the basic reasons for divorces and suicides among married partners. The *Klaibya* is a disease which affects ones normal life to a great extent by making cracks in the relation of partners and there by disturbing the peace of mind of both the partners. The *Klaibya* is one of the basic reasons for divorces and suicides among married partners.

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