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## A COMPARATIVE CLINICAL STUDY ON "TO EVALUATE THE EFFICACY OF AMALAKA YOGA AND ZECO 100 TABLETS IN THE MANAGEMENT OF KLAIBYA WITH SPECIAL REFERENCE TO ERECTILE DYSFUNCTION"

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### **Abstract**

Klaibya is a multi-factorial condition, mainly involving Bahu Doshavastha as a whole and Sukrakhsaya in specific, Mano Dosa, and SukravahaSroto Dusti. A great success of married life is hidden in the sexual harmony of the couple. The common cause which always prevents a man from enjoying sexual interplay with his female partner is called as "Klaibya" in Ayurveda. The term 'Klaibya' is known as 'Erectile dysfunction (E.D.)' & is commonly known as "Impotency" in modern texts. Impotency as a medical and social problem has acquired global dimensions and its incidence is supposed to be gradually increasing by every decade. Despite great advances made by medical science in understanding the actual cause, but still this problem is persist, due to which impotency is still a catastrophe. The male sexual dysfunction includes all sorts of disturbances of coital performance in male. Among the various phases of sexual response, the most essential is the intercourse, the absence of which ends into failure and dissatisfaction. Main aim of present study was to comparatively assess the efficacy of *Amalaka Yoga* and *Zeco100 tablets* in the patients of Klaibya. For the above purpose 60 patients were selected and randomly divided into two groups, each group had been 30 patients. It can be concluded that the Klaibya can be better managed by administration of zeco 100 tablets.

## Introduction:-

- In Ayurveda, Purusharthas are Dharma, Artha, Kaama and Moksha. They are said to be the main objects of life. The well-known and ancient authoritative text of Indian erotic literature *Kaama Sutra* of Acharya Vatsyana considers Kaama (love and sex) as an art. This literature deals with all the aspects of love and sex, with its personal, social, cultural and medical importance. It has been mentioned about 64 art forms of sex where more importance is given to fore play, before actual sexual intercourse. According to Charaka<sup>1</sup> Causes involve the lack of sex desire, Premature ejaculation, Thin and odourless semen, Mental factors like fear, anxiety, stress and tension which lead to disturbed physical and mental health status in the form of difficulty in breathing, excessive sweating, tiredness followed by lack of penile rigidity and thus his attempts to have sex ends with frustration and failure. Charaka<sup>2</sup> types it as beejopaghaataja, dhvajopaghaataja, shukrakshayaaja and jaraajanya. Modern causes include<sup>3</sup>- Heart disease, Clogged blood vessels (atherosclerosis), High cholesterol, High blood pressure, Diabetes, Obesity etc. and complications like unsatisfactory sex life, infertility etc.
- Amalaka yoga <sup>4</sup> has been advised in the patients of Klaibya (E.D.) as per Susruta Samhita. It is the dry powder of Amalaki poured in Amalaki Swarasa. It should be taken by mixing with Madhu, Sharkara, and Ghrita. After taking it, a glass of milk should be drunk as Anupana. Zeco 100 tablets<sup>5</sup> containing ashwagandha, shatavari, balaamoola etc is compared to achieve the thickness of semen followed by improvement in klaibya.
- The single blind comparative clinical trials offered in the parallel study are not yielding satisfactory results and are not free from side effects. Hence there is a need to find a better cure as the patients are not only physically but mentally weak too.

### **Aims and objectives:-**

1. To evaluate the efficacy of Amalaka Yoga in the management of Klaibya.
2. To evaluate the efficacy of Zeco 100 tablets in the management of Klaibya.
3. To compare the efficacy of Amalaka Yoga and Zeco 100 tablets in the management of Klaibya.

### **Study Design –**

#### ***Inclusion Criteria - Married male patients***

1. In the age of 21-60 years.
2. Having signs and symptoms of Klaibya.
3. Getting Ejaculation before or just after penetration.
4. Unable to achieve partner's satisfaction.

#### ***Exclusion Criteria- Married male patients***

1. Diagnosed with chronic disease likes severe hypertension, IHD, COPD, etc.
2. Diagnosed with sexually transmitted diseases.
3. Diagnosed with Erectile dysfunction due to nerve damage ex. Accidental injury like spinal cord injury.
4. Undergone surgery of colon, prostate, bladder and rectum.
5. Having heavy smoking

#### ***Discontinuation Criteria***

1. Appearance of Complication between the trial periods.
2. Persons not willing to continue.

### **Material And Methods: -**

All the 60 Patients were selected & randomly assigned into two groups as group A & group B with 30 patients in each group.

### **Group A: Amalaka Yoga**

Amalaka Yoga described in Ksheena-BaliyaVajikaranamAdhyaya of Susruta Samhita,ChikitsaSthana (Su.Chi. 26/24-25) was taken for the study.

The above control drug was composed of following ingredients-

1. Amalaka Yoga
2. Sharkara
3. Madhu
4. Ghrita
5. Dhugdha (anupana)

### **Method: -**

The patient was given 6 grams of Amalaka Yoga mixed with Sharkara, Madhu, Ghrita and with Anupana of Dhugdha twice daily in morning and at night after food for 6 weeks.

### **Group B: Zeco 100 tablets**

The Zeco 100 tablets, Batch no.768, Manufacturing date – 9/19, Expiry date – 8/23 was borrowed from GMP certified pharmacy “Health Orbit, life sciences, B.H.S. Nagar, Dugri, ludhiyana”.

The above trial drug was composed of following ingredients-

1. Ashwagndha – 30 gms
2. Shatavari – 50 gms
3. Balaamoola – 40 gms
4. Safed mushali – 70 gms
5. Mukta shukti – 30 gms
6. Kuchlashudha – 3 gms
7. Vanga bhasma – 3 gmsetc
8. Dhugdha (anupana)

**Method: -**

The patient was given two tablets of zeco 100 with Anupana of Dugdha twice daily in morning & at night after food for 6 weeks.

**Data collection and monitoring**

Follow ups- Once in every 15 days. i.e., Before treatment one visit (0<sup>th</sup> day), During treatment three F/Us (15<sup>th</sup>, 30<sup>th</sup> & 45<sup>th</sup> day) & After treatment One F/U (60<sup>th</sup> day) i.e., one visit & 4 follow ups in total were taken.

**Criteria for Assessment of Result-****Subjective Parameters with scores allotted**

These subjective parameters were assessed BT (0<sup>th</sup> d), DT (15<sup>th</sup>, 30<sup>th</sup> & 45<sup>th</sup> d) & AT (60<sup>th</sup> d)

AC SPM	Findings	Gr	AC SPM	Findings	Gr
1. GOL <sub>6</sub>	Excellent (Spn): < 6.2"	0	2. GOG <sub>7</sub>	Excellent (Spn): < 5.1"	0
	Normal: 4.2" > 6.2"	1		Normal: 4" > 5.1"	1
	Mild (Sbn): 3.6" > 4.2"	2		Mild (Sbn): 3.6" > 4"	2
	Moderate (P): 3.6"	3		Moderate (P): 3.6"	3
	Severe (Mp): > 3.6"	4		Severe (Mp): > 3.6"	4
3. GOH <sub>8</sub>	Excellent (Rock Hard)	0	4. ET <sub>9</sub>	Excellent: < 11 min	0
	Normal (Completely hard & fully rigid)	1		Normal: 3 > 11 min	1
	Mild (Hard enough for vaginal penetration)	2		Mild: 60 sec > 3 min (PME)	2
	Moderate (Hard but not enough for vaginal penetration)	3		Moderate: 15 sec > 60 sec (PME)	3

	Severe (Not Hard)	4		Severe: > 15 sec / Before vaginal penetration (PME)	4
5. 10	SS	Excellent (Too Long): 13 > 30 min	0		
		Normal (Desirable): 7 > 13 min)	1		
		Mild (Adequate): 3 > 7 min)	2		
		Moderate (Short): 1 > 3 min	3		
		Severe (Too short): > 1 min	4		

**AC**-Assessment criteria, **SPM**- Subjective parameters, **BT**-Before treatment, **DT**-During treatment, **F/U**- follow up, **AT**-After treatment, **Gr**-Gradings, **GOL**-Genital organ length, **GOG**-Genital organ girth, **GOH**-Genital organ hardness, **ET**-Ejaculation time, **SS**-Sexual satisfaction, **Spn**-supernormal, **Sbn**-subnormal, **P**-placid, **Mp**-Micropenis, **PME**-Premature ejaculation

### Result:-

**Table 1 :-**Effect of the therapy in Subjective Parameters in Group A

Group A	Mean		Mean Diff	% Relief	SD	SE	P Value	Sig.
	BT	AT						
GOL	1.700	2.767	1.067	62.76	0.4498	0.0821	0.0001	HS
GOG	1.800	2.533	0.7333	40.74	0.5208	0.09509	0.0001	HS
GOH	1.633	2.233	0.600	36.73	0.4983	0.09097	0.0001	HS
ET	1.600	2.200	0.600	37.50	0.5632	0.1028	0.0001	HS
SS	1.767	2.367	0.600	33.96	0.5632	0.1028	0.0001	HS

**Table 2 :-**Effect of the therapy in Subjective Parameters in Group B

Group A	Mean		Mean Diff	% Relief	SD	SE	P Value	Sig.
	BT	AT						
GOL	1.533	2.633	1.10	71.75	0.4026	0.07350	0.0001	HS
GOG	1.733	2.900	1.167	67.33	0.3790	0.06920	0.0001	HS
GOH	1.733	2.667	0.933	55.77	0.4498	0.08212	0.0001	HS
ET	1.667	2.700	1.033	62.00	0.4901	0.08949	0.0001	HS
SS	1.600	2.567	0.9667	60.42	0.4138	0.07556	0.0001	HS

**Table 3 :-**Percentage wise relief of subjective parameters in Group A and Group B

Subjective parameters	% Relief in Group A	% Relief in Group B
GOL	62.76	71.75
GOG	40.74	67.33
GOH	36.73	55.77
ET	37.50	62.00
SS	33.96	60.42

**Table 4 :-**The overall effect of the therapy

Effects	Group A		Group B	
	No. of Patients	%	No. of Patients	%
Excellent relief	00	00	06	20
Normal (Significant) relief	11	36.66	15	50
Mild relief	05	16.67	00	00
Moderate relief	14	46.67	09	30
Severe (No relief / Unchanged)	00	00	00	00

## **Discussion:-**

### ***Discussion on results***

The effect of therapy was assessed on each symptom of the disease in both the groups as follows-

#### **Effect of Therapy on GOL Score:**

1. In **Group A** the mean Score before treatment was 1.700 which improved to 2.767 after the treatment. The relief was 62.76% which was statistically highly significant ( $p < 0.0001$ ).
2. In **Group B** the mean Score before treatment was 1.533 which improved to 2.633 after the treatment. The relief was 71.75% which was statistically highly significant ( $p < 0.0001$ ).
3. This is clear from the above discussion that the therapies given to Group A and Group B improved the GOLQ: 1, but it was more in Group B in comparison to Group A.
4. In comparison there is statistically insignificant ( $p > 0.05$ ) difference was found.

#### **Effect of Therapy on GOG Score:**

1. In **Group A** the mean Score before treatment was 1.800 which improved to 2.533 after the treatment. The relief was 40.74% which was statistically highly significant ( $p < 0.0001$ ).
2. In **Group B** the mean Score before treatment was 1.733 which improved to 2.900 after the treatment. The relief was 67.33% which was statistically highly significant ( $p < 0.0001$ ).
3. This is clear from the above discussion that all the therapies given to Group A and group B improved the GOGQ: 2, but it was more in Group B in comparison to Group A.
4. In comparison there is statistically highly significant ( $p < 0.001$ ) difference was found.



### **Effect of Therapy on GOH Score:**

1. In the **Group A** the mean Score before treatment was 1.633 which improved to 2.233 after the treatment. The relief was 36.73% which was statistically highly significant ( $p<0.0001$ ).
2. In the **Group B** the mean Score before treatment was 1.733 which improved to 2.667 after the treatment. The relief was 55.77% which was statistically highly significant ( $p<0.0001$ ).
3. This is clear from the above discussion that the therapies given to Group A and group B improved the GOHQ: 3, but it was more in Group B in comparison to Group A.
4. In comparison there is statistically significant ( $p<0.05$ ) difference was found.

### **Effect of Therapy on ET Score:**

1. In the **Group A** the mean Score before treatment was 1.600 which improved to 2.200 after the treatment. The relief was 37.50% which was statistically highly significant ( $p<0.0001$ ).
2. In the **Group B** the mean Score before treatment was 1.667 which improved to 2.700 after the treatment. The relief was 62.00% which was statistically highly significant ( $p<0.0001$ ).
3. This is clear from the above discussion that the therapies given to Group A and Group B improved the ETQ: 4, but it was more in Group B in comparison to Group A.
4. In comparison there is statistically moderately significant ( $p<0.01$ ) difference was found.

### **Effect of Therapy on SS Score:**

1. In the **Group A** the mean Score before treatment was 1.767 which improved to 2.367 after the treatment. The relief was 33.96% which was statistically highly significant ( $p<0.0001$ ).

2. In the **Group B** the mean Score before treatment was 1.600 which improved to 2.567 after the treatment. The relief was 60.42% which was statistically highly significant ( $p < 0.0001$ ).
3. This is clear from the above discussion that the therapies given to Group A and Group B improved the SSQ:5, but it was more in Group B in comparison to Group A.
4. In comparison there is statistically moderately significant ( $p < 0.01$ ) difference was found.

### ***Probable mode of action of the therapy***

### ***Discussion on Amalaka Yoga (Su.Chi.26/24)***

Various medicinal yoga are described in classical literatures of Ayurveda, study drug formulation has been selected from SusrutaChikitsasthanaKsheena-BaliyaVajikaranam chapter. This chapter devoted for description of treatment remedy of sexual diseases.

1. Amala is having Amla and Madhura Rasa, Madhura Vipaka and Guru and Sheeta Guna. These properties make it Dhatu Pushtikaraka. Amalaka is well known for its Pittashamak action.
2. Dugdha is well known aphrodisiac and life stabilizer drug. Considering chronicity and nature of the disease, it is very useful for treating the disease and also maintaining the general health of the patients. Due to chronic nature of the disease, the patients remain in the state of general debility (Dourbalya). Being Rasayana, Dugdha improves the quality of Dhatu produced and also brings the Dushti of Dhatu (Dusya) to a normal state <sup>11</sup>. All these properties improve the general health of the patient, promotes the strength of the body, the mind and there by helps in managing the Klabhya.
3. Ghrita with its SheetaVirya and Rasayana properties helps in improving all the Dhatus. Ghrita is proved to be beneficial for aphrodisiac purpose and delays the ageing <sup>12</sup>.
4. Sharkra is Madhura in Rasa, Balya, Dahanashak and Shukrala. <sup>13</sup>So, it is useful in increasing the stamina and therefore helps in the management of the Klabhya.

5. Madhu is having Yogavahi, Vrishya and Srotosodhaka properties.<sup>14</sup> Due to above mentioned properties Madhu is aphrodisiac in nature. It increases the properties of other ingredients by virtue of being Yogvahi. Due to Srotosodhaka capability, it cleanses the channels of the body, so as to facilitate the easy reach of other drugs throughout the body especially, in the Shukravahasrotasa.
6. The entire component in Amalaka Yoga having Madhura Rasa, Madhura Vipaka and SheetaVirya. All above properties Dravya act as Dhatupushtikar, Vaajikaran and Bhrimana effect.

### ***Discussion on Zeco 100 tablets***

1. It is indicated in scanty semen & extreme sexual debility.
2. It acts on general physical weakness and nervous debility due to excessive wastage of semen
3. It is also indicated in discharge of semen with urine.

### **Conclusion:-**

Total 60 patients were selected for study which were randomly divided into 2 equal groups i.e. Group A and Group B. The patients of Group A were administered Amalaka Yoga with Sharkara, Madhu, Ghrita along with Anupana of Dugdha and the patients of Group B were administered zeco 100 tablets for 6 weeks along with follow up on every 2 weeks. Results had been assessed on the basis of designed subjective parameters. The data obtained after the completion of treatment was statistically analysed and it was found that the results were statistically highly significance in the both groups.

While comparing the results the patients of Group B have shown better results as compared to the Group A. Hence, it can be concluded that the Klaibya can be better managed by administration of the zeco 100 tablets.

### **BIBLIOGRAPHY :**

1. Maharshi Agniveshakrita, dradhabalasampoorita, charakapratisanskrita CHARAKA SANHITA (atreyapunarvasupercepted ) - Charaka Chandrika hindi commentary by

- Dr Brahmanand Tripathi - forwarded by Dr Prabhakar janardandeshpande. volume 2<sup>nd</sup>, published by Choukhambhasurabharatiprakashan - varanasi, 5<sup>th</sup> edition 1998, page no.1038, sloka no.155 to 157, Yonivyapatchikitsaaadhyaya 30<sup>th</sup> chapter, Chikitsastana.
2. Maharshi Agniveshakrita, dradhabalasampoorita, charakapratishanskrita CHARAKA SANHITA (atreyapunarvasupercepted ) - Charaka Chandrika hindi commentary by Dr brahmanandtripathi - forwarded by Dr Prabhakar janardandeshpande. volume 2<sup>nd</sup>, published by Choukhambhasurabharatiprakashan - varanasi, 5<sup>th</sup> edition 1998, page no.1038, sloka no.154, Yonivyapatchikitsaaadhyaya 30<sup>th</sup> chapter, Chikitsastana.
  3. <http://www.bumc.bu.edu/sexualmedicine/physicianinformation/epidemiology-of-ed/Nov.2002>
  4. Sushruta, SushrutaSamhita, edited with Ayurveda TatvaSandipikahindi commentary, KavirajaAmbikadutta Shastri, Chaukhambha Sanskrit Sansthan, Varanasi, Part I, Year of reprint 2010, Chikitsasthana 26/24, Pg. No. 149
  5. [healthorbit@live.com](mailto:healthorbit@live.com)1.
  6. [www.sciencemag.org](http://www.sciencemag.org)
  7. [www.sciencemag.org](http://www.sciencemag.org)
  8. [www.sexhealthmatters.org](http://www.sexhealthmatters.org)
  9. [www.emedicine.medscape.com](http://www.emedicine.medscape.com)
  10. [www.news.psu.edu](http://www.news.psu.edu)
  11. Bhavamishra, Bhavaprakash, edited with vidyoniti Hindi commentary by Pandit Shree Brahma Sankara Mishra, Chaukhambha Sanskrit Bhawan, Varanasi, Edition 12, Year of Reprint 2016, Dugadhavarga /7-8 Pg. No. 906
  12. Bhavamishra, Bhavaprakash, edited with vidyoniti Hindi commentary by Pandit Shree Brahma SankaraMishra, Chaukhambha Sanskrit Bhawan, Varanasi, Edition 12, Year of Reprint 2016, Ghritavarga /4-6 Pg. No. 922

13. Bhavamishra, Bhavaprakash, edited with vidyoniti Hindi commentary by Pandit Shree Brahma Sankara Mishra, Chaukhambha Sanskrit Bhawan, Varanasi, Edition 12, Year of Reprint 2016, Ikshuvarga /30 Pg. No. 943
14. Bhavamishra, Bhavaprakash, edited with vidyoniti Hindi commentary by Pandit Shree Brahma Sankara Mishra, Chaukhambha Sanskrit Bhawan, Varanasi, Edition 12, Year of Reprint 2016, Madhuvarga /2-5 Pg. No. 935.