RESEARCH ARTICLE

A COMPARATIVE CLINICAL STUDY ON EFFICACY OF AMALAKA YOGA AND ASHWINI MUDRA IN KLAIBYA.

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Abstract

Klaibya is a multi-factorial condition, mainly involving Bahu Doshavastha as a whole and Sukrakhaya in specific, Mano Dosa, and Sukravaha Sroto Dusti. The term 'Klaibya' is known as 'Erectile dysfunction (E.D.) in modern texts. The male sexual dysfunction includes all sorts of disturbances of coital performance and sexual congress 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 Ashwini Mudra 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 Ashwini Mudra.

Introduction:

In Ayurveda, Purushartha Chatustaya i.e. Dharma, Artha, Kama and Moksha are said to be the main objects of life. The concept of Kama reveals that the recreational aspects like pleasure are equally important to its procreation aspects. Healthy sexual functioning plays essential role in maintaining the harmony and happiness in marital life. As well as healthy progeny is also totally depends on healthy sexual life. The male sexual dysfunction includes all sorts of disturbances of coital performance and sexual congress in male. Among the various phases of sexual response the most essential is the intercourse, the absence of which ends into failure and dissatisfaction. This condition is known as 'Klaibya' in Ayurvedic classics and 'Erectile dysfunction (E.D.)' in modern texts. It is a significant and common medical problem and impacts significantly on mood state, interpersonal functioning and overall quality of life.¹

Amalaka yoga² 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, Shankara, and Ghrita. After taking it, a glass of milk should be drink as Anupana. Ashwini Mudra³ is compared to the expansion and contraction of the anus that meant to achieve the maximum movement of a specific position. It tones up and strengthens of pelvic muscles and organs which are put to work during the act of ejaculation and urination in men. To gain better control, one needs to strengthen these muscles. Ashwini Mudra provides well-being of all those muscles and nerves surrounding the anus sphincters. The diseases related the urogenital organs are specially cured. Overall, Ashwini Mudra provides everything that helps you live a healthy and long sex life.

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The treatments offered in the parallel sciences 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:-**
The present research work has been started with following aims and objectives;
1. To assess the efficacy of Amalaka Yoga in the patients of Klaibya.
2. To assess the efficacy of Ashwini Mudra in the patients of Klaibya.
3. To compare efficacy of Amalaka Yoga and Ashwini Mudra in the patients of Klaibya.

**Eligibility criteria:**

**Inclusion Criteria-**
1. Married male patients in the age of 21-60 years.
2. Married male patients having sign and symptoms of Klaibya.
3. The patient having a complaint of marked reduction in sexual desire compared with normal situation.
4. Ejaculation before or just after penetration.
5. Unable to achieve partner’s satisfaction.

**Exclusion Criteria-**
1. Patient with chronic disease likes severe hypertension, IHD, COPD, etc.
2. Patients having any sexually transmitted diseases.
3. Erectile dysfunction due to nerve damage ex. Accidental injury like spinal cord injury.
4. Erectile dysfunction due to surgery of colon, prostate, bladder and rectum.
5. Heavy smokers
6. Routine pathological and biochemical investigations had been done to exclude any other major pathology.

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

**Material And Methods:-**
60 Patients were distributed into following 2 therapeutic groups with 30 patients in each group.

**Group A: Amalaka Yoga**
In this group, Amalaka Yoga was administered two times in a day. Amalaka Yoga described in Ksheena-Baliya Vajikaranam Adhyaya of Susruta Samhita Chikitsa Sthana (Su.Chi. 26/24-25) was taken for the study.

The above trial drug was composed of following ingredients-
1. Amalaka Yoga
2. Sharkara
3. Madhu
4. Ghrit
5. Dhugdha (anupana)

**Method: -**
The patient was given 6 grams of Amalaka Yoga mixed with Sharkara, Madhu, Ghrit and with Anupana of Dhugdha twice daily in morning and at night for 6 weeks.

**Group B: Ashwini Mudra**
In this group Ashwini Mudra had been advised to practice in morning and evening for 10-20 minutes.

**Method:-**
1. Patients were advised to sit in the comfortable meditative asana e.g. Siddhasana, Padmasana, Swastikasana etc, best pose being Padmasana.
2. To close the eyes, relax the whole body and breathe normally. Then patient was asked to keep the awareness on breathing and the anus.
3. To rapidly contract the anal sphincter muscles for a few seconds without straining and relax them.
4. To confine the action to the anal area.
5. Repeating for at least 10 rounds.

Data collection and monitoring
Follow up done after each 2 weeks for 6 weeks i.e. 4 follow ups in total were taken.

Criteria for Assessment of Result-
Subjective Parameters-
The International Index of Erectile Function 15 items (IIEF-15) has been used at baseline day, 2nd week, 4th week and 6th week.

A) International Index of Erectile Function 15 items (IIEF-15)
Clinical Interpretation of IIEF 5:
Erectile function total scores can be interpreted as follows:
1. 0-6 Severe dysfunction.
2. 7-12 Moderate dysfunctions
3. 13-18 Mild to moderate dysfunction
4. 19-24 Mild dysfunctions
5. 25-30 No dysfunction

Outcome
Primary outcome-
The subjective parameters were assessed on the basis of International Index of Erectile Function (IIEF-15).
1. Erection during sexual activity
2. Hardness of erection
3. Maintenance of erection

Result:
Table I:- Effect of the therapy in Subjective Parameters in Group A

<table>
<thead>
<tr>
<th>Group A</th>
<th>Mean</th>
<th>Mean</th>
<th>% Relief</th>
<th>SD</th>
<th>SE</th>
<th>P Value</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>IIEF Q:1</td>
<td>1.700</td>
<td>2.767</td>
<td>1.067</td>
<td>62.76</td>
<td>0.4498</td>
<td>0.0821</td>
<td>0.0001</td>
</tr>
<tr>
<td>IIEF Q:2</td>
<td>1.800</td>
<td>2.533</td>
<td>0.733</td>
<td>40.74</td>
<td>0.5208</td>
<td>0.0950</td>
<td>0.0001</td>
</tr>
<tr>
<td>IIEF Q:3</td>
<td>1.633</td>
<td>2.233</td>
<td>0.600</td>
<td>36.73</td>
<td>0.4983</td>
<td>0.0909</td>
<td>0.0001</td>
</tr>
<tr>
<td>IIEF Q:4</td>
<td>1.600</td>
<td>2.200</td>
<td>0.600</td>
<td>37.50</td>
<td>0.5632</td>
<td>0.1028</td>
<td>0.0001</td>
</tr>
<tr>
<td>IIEF Q:5</td>
<td>1.767</td>
<td>2.367</td>
<td>0.600</td>
<td>33.96</td>
<td>0.5632</td>
<td>0.1028</td>
<td>0.0001</td>
</tr>
<tr>
<td>IIEF Q:15</td>
<td>1.633</td>
<td>2.100</td>
<td>0.4667</td>
<td>28.57</td>
<td>0.5074</td>
<td>0.0926</td>
<td>0.0001</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Group B</th>
<th>Mean</th>
<th>Mean</th>
<th>% Relief</th>
<th>SD</th>
<th>SE</th>
<th>P Value</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>IIEF Q:1</td>
<td>1.533</td>
<td>2.633</td>
<td>1.100</td>
<td>71.75</td>
<td>0.4026</td>
<td>0.0735</td>
<td>0.0001</td>
</tr>
<tr>
<td>IIEF Q:2</td>
<td>1.733</td>
<td>2.900</td>
<td>1.167</td>
<td>67.33</td>
<td>0.3790</td>
<td>0.0692</td>
<td>0.0001</td>
</tr>
<tr>
<td>IIEF Q:3</td>
<td>1.733</td>
<td>2.667</td>
<td>0.933</td>
<td>55.77</td>
<td>0.4498</td>
<td>0.0821</td>
<td>0.0001</td>
</tr>
<tr>
<td>IIEF Q:4</td>
<td>1.667</td>
<td>2.700</td>
<td>1.033</td>
<td>62.00</td>
<td>0.4901</td>
<td>0.0894</td>
<td>0.0001</td>
</tr>
<tr>
<td>IIEF Q:5</td>
<td>1.600</td>
<td>2.567</td>
<td>0.9667</td>
<td>60.42</td>
<td>0.4138</td>
<td>0.0756</td>
<td>0.0001</td>
</tr>
<tr>
<td>IIEF Q:15</td>
<td>1.600</td>
<td>2.600</td>
<td>1.000</td>
<td>62.50</td>
<td>0.5872</td>
<td>0.1072</td>
<td>0.0001</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Subjective parameters</th>
<th>% Relief in Group A</th>
<th>% Relief in Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td>IIEF Q:1</td>
<td>62.76</td>
<td>71.75</td>
</tr>
<tr>
<td>IIEF Q:2</td>
<td>40.74</td>
<td>67.33</td>
</tr>
</tbody>
</table>
Discussion:
Discussion on results
The effect of therapy was assessed on each symptom of the disease according to questionnaire. The effect of therapy in all the groups in each sign and symptom is as followings-

Effect of Therapy on IIEF Q:1 Score:
1. In Group A the mean Score before treatment was 1.70 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 IIEF Q: 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 IIEF Q:2 Score:
1. In Group A the mean Score before treatment was 1.80 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 2.90 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 IIEF Q: 2, but gain 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 IIEF Q:3 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 IIEF Q: 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 IIEF Q:4 Score:
1. In the Group A the mean Score before treatment was 1.60 which improved to 2.20 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 2.70 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 IIEFQ: 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.

Table IV:-The overall effect of the therapy

<table>
<thead>
<tr>
<th>Effects</th>
<th>Group A</th>
<th></th>
<th>Group B</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No relief (Unchanged)</td>
<td>00 00.00</td>
<td>00 00.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild relief</td>
<td>05 16.67</td>
<td>00 00.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate relief</td>
<td>14 46.67</td>
<td>09 30.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Significant relief</td>
<td>11 36.66</td>
<td>15 50.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Excellent relief</td>
<td>00 00.00</td>
<td>06 20.00</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Effect of Therapy on IIEF Q:5 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 1.60 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 IIEF Q: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.

Effect of Therapy on IIEF Q:15 Score:
1. In the Group A the mean Score before treatment was 1.633 which improved to 2.10 after the treatment. The relief was 28.57% which was statistically highly significant (p<0.0001).
2. In the Group B the mean Score before treatment was 1.60 which improved to 2.60 after the treatment. The relief was 62.50% 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 IIEF Q:15, but it was more in Group B in comparison to Group A.
4. In comparison there is statistically highly significant (p<0.0001) 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 Susruta Chikitsa sthana Ksheena-Baliya Vajikaranam 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 Pushitkaraka. 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 Dushhti of Dhatu (Dusya) to a normal state. 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 Klaibya.
3. Ghrita with its Sheeta Virya and Rasayana properties helps in improving all the Dhatus. Ghrita is proved to be beneficial for aphrodisiac purpose and delays the ageing.
4. 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.
5. Madhu is having Yogavahi, Vrishya and Srotosodhaka properties. 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 Shukravaha srotasa.
6. The entire component in Amalaka Yoga having Madhura Rasa, Madhura Vipaka and Sheeta Virya. All above properties Dravya act as Dhatupushtikar, Vaajikaran and Bhrimana effect.

Discussion on Ashwini Mudra
1. Ashwini Mudra has been described in Gherand Samhita.
2. It is the rhythmic contraction and relaxation of perianal muscles.
3. It is also preparatory procedure for Moolbandha.
4. Ashwini Mudra has therapeutic effect on sexual problems according to Gherand Samhita.
5. It strengthens the pelvic floor muscles which play important role in initiation and maintenance of penile erection.

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 had been advised to practice Ashwini Mudra for 6 weeks along with follow up on every 2 weeks. Results had been assessed on the basis of IIEF-15. The data obtained after the completion of
treatment was statistically analyzed 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 Ashwini Mudra.

References:
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5. 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