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CLINICAL EVALUATION OF AYURVEDIC FORMULATION (JEEHV) FOR ITS OVULATION PROMOTING ACTION IN FEMALES SUFFERING FROM ANOVULATION

¹*Dr. Aarati Patil, ²Dr. Divya C. S. and ³Dr. Gauri More

^{1,2}M.S. Prasuti-Tantra and Stree-Roga. ³M.D. Kriya-Sharir, Dhanwantari Ayurveda Centre, Lokhandwala, Andheri West, Mumbai.

*Corresponding Author: Dr. Aarati Patil

M.S., Prasuti-Tantra and Stree-Roga.

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ABSTRACT

Objective- The objective of the study was to evaluate efficacy of an Ayurvedic Formulation – Jeehv Tablets in females suffering from ovulation related problems (delayed or anovulation). Materials & Method - A total of 149 female patients between the age of 25-35 years having complaints of delayed or irregular menstrual cycle along with improper ovulation/delayed ovulation or anovulation were recruited in the study. Participants who even had a regular menstrual cycle but were non able to achieve ovulation were also considered for assessment. Participants who had consumed Jeehv tablets for more than 2 months were evaluated for their response related to ovulation. These participants were consuming Jeehv tablets in a dose of 2 tablets twice daily with water. Follow up was done at an interval of 1 month, 2 months and 3 months to assess if participants had ovulated on the basis of a simple urine test for ovulation (home ovulation detection kit). Participants were asked to carry our urinary ovulation test from 12th to 20th day after achieving menstruation on alternate days. Participants having any serious abnormalities were excluded from the study. Jeehv Tablets is proprietary Ayurvedic formulation containing ingredients like Jeevanti, Putrajivaka, Shivlingi beej, Aloe vera. **Results** – Female participants of average age 28.56 ± 4.16 with or without complaint of irregular menstrual cycle but having complaints of not achieving ovulation were assessed in the study. The average duration of these participants not achieving timely ovulation was 8.45 ± 2.23 months. A total of 127/149 (85.23%) participants reported achieving ovulation on time after consuming Jeehv tablets. Also, 123 subjects (82.55%) had complaints of irregular menstrual cycle which was normalized in 98 subjects. The average time of achieving ovulation in the participants was observed to be 76.45 ±21.22 days. No adverse drug reaction was observed and the study products were well tolerated. Conclusion- Ayurvedic tablets (Jeehv) were found to be effective in assisting timely ovulation and thus can be useful in the management of infertility associated with gynecological disorders like PCOS, Irregular periods etc. The product was also found to be safe without causing any adverse effects.

KEYWORDS: Jeehv Tablets, Ovulation, PCOS.

INTRODUCTION

Infertility is a disease of the male or female reproductive system defined by the failure to achieve a pregnancy after 12 months or more of regular unprotected sexual intercourse1. The incidence of infertility is on rise world wide affecting millions of people of reproductive age and has an impact on their families and communities. Estimates suggest that between 48 million couples and 186 million individuals live with infertility globally (2, 3, 4). Infertility in females may be caused by a range of abnormalities of the ovaries, uterus, fallopian tubes, and the endocrine system, among others. Infertility can be primary or secondary. Primary infertility is when a person has never achieved a pregnancy, and secondary infertility is when at least one prior pregnancy has been achieved.

Management of infertility depends on the underlying cause for it. Ovulating infrequently or not at all accounts for most cases of infertility. Problems with the regulation of reproductive hormones by the hypothalamus or the pituitary gland or problems in the ovary can cause ovulation disorders. Polycystic ovary syndrome (PCOS), Hypothalamic dysfunction, Primary ovarian insufficiency, and too much prolactin are the leading causes of infertility in females. Increasing age, Smoking, Obesity and sexual history are other common factors to be considered while diagnosing and treating cases of infertility.

Ayurveda mentions *Vandhyatva* as a condition in which a female is unable to conceive. Ayurvedic herbs and formulations have been used since ages for the management of infertility. The concept of stimulating ovulation very much exists in Ayurveda. The Ayurvedic philosophy of management of infertility targets to improve the quality and timely secretion of ova referred to as "beej" in Ayurveda. Herbs like Shivilingi beej, Aloe vera, Putrajeevak have been recommended in Ayurveda for the purpose of bringing about ovulation.

The present study evaluates the effect of an Ayurvedic Proprietary Formulation viz. Jeehv in females desirous of conceiving and are not able to do so due to ovulation related problems like irregular, delayed or anovulation.

OBJECTIVES

The current in-clinic response study was aimed to evaluate the clinical efficacy of Jeehv Ayurvedic Tablets in females suffering from anovulation.

MATERIALS AND METHODS

a. Study design

Retrospective, open labeled, single centric, non comparative clinical study.

b. Sample size

A total of 149 participants were reviewed who had been prescribed Jeehv Tablets for ovulation related complaints (delayed ovulation or anovulation) for a period of 3 months.

c. Study site

Patients visiting OPD of Dhanwantari Ayurveda Centre, Pallakad, Kerala, India, suffering from ovulation related issues were recommended, Jeehv Tablets were considered for analysis in this study.

d. Details of study product

i. Name of the Product – Jeehv Ayurvedic Tablets manufactured and marketed by Gynoveda Pvt. Ltd as Ayurvedic Proprietary Medicine

ii. Key Ingredients - Jeevanti, Putrajivaka, Shivlingi bej, Aloe vera etc. Detailed composition in Table

iii. Recommended dosage -2 Tablets two times a day with warm water after meals for a period of 90 Days.

e. Inclusion criteria

Non-pregnant, non-breastfeeding females between the ages of 25 and 35 years, (both inclusive), with presenting

Table	1:	Baseline	demography.
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complaints of delayed or irregular menstrual cycle along with improper ovulation/delayed ovulation or anovulation were considered for evaluation in the study. Participants who even had a regular menstrual cycle but were non able to achieve ovulation were also considered for assessment.

f. Exclusion criteria

Patients suffering from amenorrhea, dysmenorrhea for more than 1 year were excluded from the study. Patients suffering from any condition requiring surgical management immediately or within 3 months of diagnosis were excluded from the study. Patients uncontrolled hypothyroidism. suffering from uncontrolled diabetes or hypertension were excluded from the study. Patients on Oral Contraceptive Pills or IUCD (Intrauterine Contraceptive Device) for the last one month were excluded. Any other condition due to which patients were deemed unsuitable by the investigator for reason(s) not specifically stated in the exclusion criteria. Patients suffering from any acute or chronic medical or surgical condition requiring regular and continuous medical care and management were excluded from the study. Patients who were non compliant to the study requirement (like not taking regular medicines) were also excluded from this evaluation.

OBSERVATIONS AND RESULTS

A. Baseline demography

A total of 149 patients were considered for assessment of efficacy and safety in the study. The average age of participants was observed to be 28.56 ± 4.16 (range 25 to 35 years). The average duration of these participants not achieving timely ovulation was 8.45 ± 2.23 months. The mean weight of participants at baseline was 62.14 ± 6.19 Kg, with an BMI of 24.15 ± 2.95 . A total of 103 participants (69.12%) were married while 46 participants (30.87%) were unmarried. A total of 90 patients (60.40%) had a history of PCOS while 123 (82.55%) subjects had complaints of irregular and delayed menstrual cycle.

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Parameter	Values			
Average age	28.56 ± 4.16 (range 25 to 35 years)			
Average Weight	62.14 ±6.19 Kg			
Average BMI	24.15 ±2.95 Wt in Kg/Ht in m ²			
Married Participants	141 (94.63%)			
Unmarried Participants	8 (5.36%)			
Average time since having anovulation	8.45 ±2.23 months			
History of PCOS	90 patients (60.40%)			
History of Irregular or Delayed Menstrual Cycle	123 (82.55%)			

B. Assessment of effect on ovulation

A total of 127/149 (85.23%) participants reported achieving ovulation after consuming Jeehv tablets. The average time of achieving ovulation in the participants was observed to be 76.45 ±21.22 days. A total of 20 subjects achieved normal ovulation after 1 month of consumption of Jeehv tablets while 67 subjects achieved ovulation after 60 days and 40 subjects achieved ovulation after 90 days of consumption of Jeehv Tablets. The table provides details.

 Table 1: Assessment of subjects achieving ovulation in 90 days period.

Total no of subjects assessed in the study	149 (100%)
Total number of subjects achieved ovulation in the study	127 (85.23%)
No of subjects achieved ovulation within 30 days of consuming Jeehv Tablets	20 (13.42%)
No of subjects achieved ovulation within 60 days of consuming Jeehv Tablets	67 (44.96%)
No of subjects achieved ovulation within 90 days of consuming Jeehv Tablets	40 (26.84%)

C. Assessment of effect on menstrual cycle

i. At the baseline, there were 123 subjects who complained of irregular or delayed menstrual cycle. At the end of the study the menstrual cycle was regularized in 98 subjects while the other 25 subjects continued to have irregular or delayed cycles.

ii. The average number of days of bleeding at the baseline visit was 1.12 ± 0.23 which increased to 2.23 ± 1.23 at the end of 30 days and further to 2.90 ± 1.24 at the end of 60 days and 3.34 ± 1.56 at the end of 90 days. This signifies that the quantity of bleeding per cycle also improved significantly. Refer Table 2.

iii. The average frequency of menstrual cycle also improved from a baseline of 78.23 ± 23.34 days to 35.13 ± 10.23 days at the end of the study, showing significant improvement.

Table 2: Assessment of average bleeding days over 90days period.

Average bleeding days at baseline	1.12 ±0.23
Bleeding days after 30 days	2.23 ±1.23 (p<0.05)
Bleeding days after 60 days	2.90 ±1.24 (p<0.05)
Bleeding days after 90 days	3.34 ±1.56 (p<0.05)

D. Assessment of adverse effects

None of the patients experienced any adverse drug reaction due to the consumption of Jeehv Tablets in a dose of 2 tablets twice daily over a period of 90 days. The vitals assessment of pulse, respiration rate, blood pressure and temperature also did not show any significant difference and the levels were within normal range throughout the study period.

DISCUSSION

The present study evaluated the effect of an Ayurvedic proprietary formulation viz. Jeevh in cases of females suffering from ovulation related problems like missed ovulation, infrequent ovulation or anovulation. The results of the study showed that regular use of this formulation brings about ovulation as recorded by the urinary ovulation kit used by participants. Apart from this it was also observed that there was regularization of the menstrual cycle along with a positive effect of improving the quantity and duration of menstrual secretion. According to Avurveda. the disease Vandyatwa to Nashtartava where Avarana of Artavavah a srotasa becomes the chief causative factor. Ayurveda mentions extensive use of herbs that bring about ovulation by virtue of their stimulating action on the ovaries. These herbs help to restore balance of the doshas and improve the function of Artava vaha strotas as mentioned in Ayurveda. Also Ayurvedic herbs act to impart strength to the entire reproductive system. The same is referred to as Garbha shaya balya and Poshak. Jeevh is an Ayurvedic formulation containing ingredients like Shivlingi, Putraveevak, Aloe vera amongst others. These ingredients have been extensively studied for their effect on ovulation and menstruation. These ingredients stimulate the ovaries to bring about ovulation, help to reduce the inflammation, provide strength to the uterus and also regulate the flow of menstruation. The combined effect of these thus help in the management of infertility and other conditions associated with infertility like PCOS etc.

CONCLUSION

Ayurvedic tablets (Jeehv) were found to be effective in assisting timely ovulation and thus can be useful in the management of infertility associated with PCOS, Irregular periods etc. The product was also found to be safe without causing any adverse effects.

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