

A SINGLE ARM CLINICAL STUDY TO EVALUATE THE EFFICACY OF SHATAPUSHPA TAILA IN ARTAVA KSHAYA

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ABSTRACT

Artava Kshaya is characterized by *Yathochita Kala Adarshanam*, *Alpata* and *Yoni vedana*.^[1] In Modern, among menstrual disorders, Oligomenorrhea and Hypomenorrhea can be compared to some extent on the basis of its signs and symptoms. The present clinical trial was carried out on *Artava Kshaya* subjects aged between 16 to 40 years having complaints of prolonged intermenstrual period, scanty and painful menstruations. *Shatapushpa Taila* in a dose of 20 ml with luke warm water once daily morning in empty stomach was administered for two consecutive menstrual cycles among 30 subjects fulfilling the diagnostic criteria. The clinical assessment was carried out on fifth day of first two consecutive cycle with follow up on fifth day of third cycle. The study discloses the effect of *Shatapushpa Taila* on irregularity of interval between two cycle (91%), duration of bleeding (69%), amount of blood flow (75%) and pain (63%) which were statistically highly significant in clinical study. No adverse drug

reaction was seen during the study.

KEYWORDS: *Ayurveda*, *Artava Kshaya*, *Oligomenorrhoea*, *Hypomenorrhoea*, *Shatapushpa Taila*.

INTRODUCTION

Artava Kshaya is characterized by *Yathochita Kala Adarshanam* (prolong intermenstrual period), *Alpata* (duration of menstruation is less than 3 days or amount of menstrual blood is less than 35 ml) and *Yoni Vedana* (pain in lower abdomen).^[1] In India, the incidence of

23.3% women in reproductive age suffers from menstrual irregularities. Among them Oligomenorrhea accounts 18.3% and Hypomenorrhea accounts 14%.^[2] Acharya Sushruta mentioned *Samshodhana* and *Agneya Dravya* as line of treatment of *Artava Kshaya*.^[3] *Shatapushpa Taila* is mentioned in *Kashyapa Samhita* for *Chatushprayoga* as *Pana*, *Nasya*, *Abhyanga* and *Basti* in *Artavadushti*.^[4] So the study was undertaken on *Shatapushpa Taila Pana* and to evaluate its clinical efficacy in *Artava Kshaya*.

AIM AND OBJECTIVES

The trial aimed to assess the efficacy of *Shatapushpa Taila* in *Artava Kshaya* and the objectives was to assess its efficacy on duration of bleeding, amount of bleeding and on BMI.

METHODOLOGY

Study design

Interventional single group study consisting of 30 patients suffering from *Artava Kshaya* fulfilling the inclusion and diagnostic criteria were selected for the study.

Ethical clearance

The study was carried out as per the International Conference of Harmonization Good Clinical Practices Guidelines (ICH-GCP). Written and informed consent was taken from each patient willing to participate in the trial before their registration for the study. The Institutional Clinical Ethical Committee approved this study as proposal number ICEC//AS/01 on 24/07/2021.

Selection of patients

30 *Artava Kshaya* patients aged between 16-40 years fulfilling the inclusion and diagnostic criteria were selected for the study. The patients were registered from OPD of Prasuti Tantra Evum Stree Roga, Alva's Ayurveda Medical College, Moodbidri, Dakshina Kannada, Karnataka, medical camps and other referrals. Detailed history like personal history, family history, drug history, surgical history, gynaecological and obstetrical history, completed with a general examination. All selected patients were advised to visit on fifth day of three consecutive cycles.

Selection of drugs

Shatapushpa Taila indicated for *Artava Kshaya* in *Kashyapa Samhita Kalpasthana* in *Shatapushpa Shatavari kalpadhyaya*. Raw drugs required were collected under the guidance

of *Dravyaguna* experts from the local market and was prepared at GMP certified Alva's Pharmacy, Mijar as per classical reference.

DIAGNOSTIC CRITERIA

Patients fulfilling any two of the following diagnostic criteria were selected for the study,

- a. *Yathochita Kala Adarshanam*- prolong intermenstrual period
- b. *Alpata*- duration of menstruation is less than 3 days or amount of menstrual blood is less than 35 ml
- c. *Yoni Vedana*- pain in lower abdomen

Patients fulfilling the diagnostic criteria and aged between 16 to 40 years and willing to provide informed written consent, were included for the trial. Subjects with diagnosed cases of congenital abnormalities of reproductive organs, Anaemia (Hb% < 8 gm/dl) and any major systemic diseases were excluded from the trial.

INTERVENTION

Patients were administered *Shatapushpa Taila* 20 ml^[5] once daily morning in empty stomach with luke warm water for two consecutive menstrual cycle.

Assessment Criteria: Subjective criteria were interval between cycles, duration of flow, amount of bleeding and pain in lower abdomen whereas the objective criteria was BMI; assessed based upon scoring and statistical evaluation was carried out.

Assessment of Interval between two menstrual cycles: Score 0 (>35D), 1 (36-40D), 2 (61-90D), 3 (>91D).

Assessment of duration of menstrual bleeding: Score 0 (4-7D), 1 (3D), 2 (2D), 3 (>1D).

Assessment of Amount of blood loss: Score 0 (≥ 2 pads per day with complete soaking), 1 (2 pads per day with minimum soaking), 2 (1 pad per day with minimum soaking), 3 (No need of pad).

Assessment of lower abdomen pain related with menstruation: Score 0 (No pain), 1-3 (Mild pain), 4-6 (Moderate pain), 7-10 (Severe pain).

BMI assessment has been done by following WHO criteria.^[6]

Assessment of overall effect of treatment: 0-25% (No improvement), 26-50% (Mild improvement), 51-75% (Moderate improvement), 76-100% (Marked improvement).

Assessment was done on the 5th day of each menstrual cycle for two consecutive cycles with medication. Post treatment follow up was done on the 5th day of menstruation of third cycle without medication.

Statistical Analysis

The data was collected from subject before the treatment, 5th day of 1st cycle, 2nd cycle (on completion of treatment), 3rd cycle (follow up). The assessment was done based on the detailed proforma adopting standard scoring methods of subjective and objective parameters. Analysis was done by using following statistical analysis by using Sigma stat ver. 4 software.

- Wilcoxon signed Rank Test
- Paired t-test

RESULTS

Table no 1: Results.

Variable	Mean	SD	Mean difference from BT	%	SE	WSRT value	P value	Remarks
Duration of flow	0.59	0.5	1.34	69.4	0.09	4.57	<0.001	HS
Interval between two cycles	0.15	0.36	1.58	91.3	0.07	4.63	<0.001	HS
Amount of blood loss	0.48	0.51	1.45	75.1	0.10	4.59	<0.001	HS
Pain in lower abdomen	0.41	0.5	0.72	63.7	0.10	3.97	<0.001	HS

DISCUSSION

Taila pana comes under *Abhyantara Snehapana*, which are digested and absorbed in system by lipid metabolism. From lipid metabolism cholesterol forms which produces steroid hormone in ovary. From theca cells of ovary androstenedione and testosterone are produced under the influence of LH in follicular phase. These androgens diffuse into the granulosa cells where they are aromatized under the influence of FSH to estrogens like estradiol and estrone. After ovulation, progesterone is synthesized in luteinized granulosa cells under the influence of LH. Estrogen acts in the endometrium by inducing mucosal proliferation during the proliferative phase. Progesterone maintains the endothelial lining in the endometrium, resulting in thickened endometrial wall which increases the amount of bleeding by normalizing menstruation. *Shatapushpa* content phytoestrogens like isoflavones, β -estradiol which are estrogen like compounds which stimulates the regenerations of the surface endometrial epithelium. *Shatapushpa* and *Tila Taila* have anti spasmodic, analgesic property

by which it helps in reducing the pain. Both the drug contains antioxidant property which improves general health.

Shatapushpa has *Katu*, *Tikta Rasa* which is *Kapha Shamaka*, so it removes the *Avarodha* from *Artava Vaha Srotas* and increases blood circulation. *Katu Rasa* have *Rakta Sravakara* property and *Tikta Rasa* have *Rakta Shodhaka* property so amount of blood flow increases and proper amount of bleeding also occurs. *Tikta Rasa* have *Lekhana* property which exfoliate the endometrial lining. *Shatapushpa* by *Artavajanaka* property directly act on formation of *Artava*.

Tila possess *Suksma*, *Vyavayi*, *Vikasi Guna* and it is also *Sroto Vishodhaka* by which it can act in minute channels, and thus helps in proper *Rasa Chankramana*.

Tila Taila by *Snigdha*, *Guru Guna*, *Madhura Rasa* and *Vipaka* is *Vata Shamaka* in nature and *Shatapushpa* by *Yonishoolaghna*, *Vedanasthapana* property acts on relieving pain during menstruation.

Both the drug by *Deepana* property and *Ushna Virya* which causes *Niramikarana* by acting on *Agni* which further leads to formation of proper *Rasa Dhatu* and formation of proper *Upadhatu* i.e. *Artava*.

Overall effect of therapy

The study discloses the effect of *Shatapushpa Taila* on irregularity of interval between two cycle (91%), duration of bleeding (69%), amount of blood flow (75%) and pain (63%) which are statistically highly significant in clinical study. No adverse drug reaction was seen during the study.

CONCLUSION

Based on the present study *Shatapushpa Taila* on oral administration showed statistically highly significant result in *Artava Kshaya*. *Shatapushpa taila* showed statistically highly significant result in increasing amount of bleeding, normalizing the duration of flow, regularizing interval between cycle and reducing pain during menstruation without any adverse drug reaction.

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