



## A RANDOMIZED CONTROLLED CLINICAL STUDY TO EVALUATE THE EFFICACY OF ARKAPUSHPA TAILA MATRABASTI IN THE MANAGEMENT OF ARTAVAKSHAYA W.S.R TO OLIGOMENORRHEA

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### ABSTRACT

**Background:** It is a well-known fact that metabolic disorders have risen to numbers that never existed before. Oligomenorrhea, considered as *Artavakshaya* in this study, is one of the forms of expression of metabolic diseases originating from the current lifestyle. An attempt is made to reverse this pathogenesis through the *Matrabasti* modality. **Objectives:** To compare the effect of *Arkapushpa taila* and *Shatapushpa taila matrabasti* in the management of *Artavakshaya* and to discuss and draw conclusions on the effectiveness of both managements.

**Methods:** In the present study, 30 subjects were randomly selected and divided into two groups, with 15 subjects each. Group A and Group B subjects were given *Matrabasti* with *Arkapushpa* and *Shatapushpa taila* respectively for 7 days each. For every subject, subjective parameters were graded, and assessment was done on the day of the visit, after treatment, and during follow-up. **Results:** The overall assessment of parameters showed a 40% and 58.35% reduction in symptoms in Group A and Group B respectively. **Conclusion:** Group B has shown better results than Group A. The reason could be *Katu rasa* and *Tikshna guna*.

**Keywords:** *Artavakshaya*, Oligomenorrhea, *Matrabasti*

## INTRODUCTION

Women's health is a primary factor to be considered for the wellbeing of family, society, and culture. Menstrual cycle patterns can have a direct influence on physical well-being, including ovarian function, pregnancy maintenance, cardio-vascular disease, migraine, diabetes mellitus, and breast cancer. Healthy, regular menstruation is a representation of the hormonal & gynecological health of a female reproductive system<sup>1</sup>. Due to an altered lifestyle, and increased physical and emotional stress there is an alteration in the physiology of "The hypothalamo-Pituitary-Ovarian axis, which leads to several gynaecological problems. Among them, the most common is menstrual irregularity, especially in the form of *Artava kshaya*<sup>1</sup>. *Artava kshaya* is referred to as a condition in which menstruation fails to occur at the appropriate time (delayed) with the scanty flow and does not last for 3 days<sup>2</sup>. A similar entity in modern classics where menstrual bleeding occurs more than 35days apart and which remains constant at that frequency is called Oligomenorrhea<sup>3</sup>. The treatment opted for in the modern system of medicine is hormonal therapy, which can have adverse effects on the body like obesity, nausea, vomiting, hot flushes, fatigue, weight gain, breast tenderness, endometrial cancer, and breast cancer<sup>4</sup>. *Ayurveda* treatment for this condition involves *ushna*, and *teekshna* drugs in various modes of drug administration as mentioned in *Ayurvedic* classics. Among them, *Matrabasti* was selected for this study. *Anuvasana basti* is a type of *Sneha basti* and *Matrabasti* is a type of *Anuvasana basti*, which can be administered easily and has no complications, and it is also recommended for routine use in those affected with *Vata vikara*<sup>5</sup>. Group-A was administered with *Arka-pushpa taila* (trial), whereas Group-B was administered with *Shatapushpa taila* (Control). *Arkapushpa taila* is a single drug preparation. There is no scarcity with regard to the availability of *dravya*. Preparation of *Taila* is also easy and cost-effective.

## OBJECTIVES

- To evaluate the effect of *Arkapushpa taila matrabasti* in the management of *Artavakshaya*
- To re-evaluate the effect of *Shatapushpa taila matrabasti* in the management of *Artavakshaya*
- To compare the efficacy of *Arkapushpa taila* and *Shatapushpa taila matrabasti* in the management of *Artavakshaya*

## MATERIALS AND METHODS

### Source of data

**Drug source:** *Arkapushpa* for the study was collected from the premises of Sri Sri college & *Shatapushpa* from Amruthkesari drug store. "*Arkapushpa taila*" and "*Shatapushpa taila*" were prepared in the pharmacy of *Rasashastra* and *Bhaishjya Kalpana* of Sri Sri College of Ayurvedic Science and Research Hospital, Bengaluru.

**Sample source:** Patients fulfilling the diagnostic criteria irrespective of their religion, caste, race, or socio-economic status were taken from OP & IP department of *Prasuti Tantra & Streeroga* of Sri Sri College of Ayurvedic Science and Research Hospital, Bengaluru.

**Sample size:** 30

**Study design:** A simple randomized open-label controlled clinical study.

### METHOD OF COLLECTION OF DATA:

- Simple random sampling.
- 30 patients fulfilling the diagnostic criteria of *Artavakshaya* were selected and randomly categorized using the lottery method.

Group A - 15 patients were subjected to *Arkapushpa taila matrabasti*.

Group B - 15 patients were subjected to *Shatapushpa taila matrabasti*.

- A separate case proforma was prepared with details of history taking, signs, and symptoms of *Artavakshaya* according to *Ayurvedic* and Modern literature.
- Lab investigations were done according to necessity and the findings were documented.

**Table No. 1 – Showing intervention schedule.**

	<b>GROUP A</b>	<b>GROUP B</b>
<b>Medicine</b>	<i>Arkapushpa taila</i>	<i>Shatapushpa taila</i>
<b>Mode of administration</b>	<i>Matrabasti</i>	<i>Matrabasti</i>
<b>Dose</b>	$\frac{1}{2}$ pala (72ml)	$\frac{1}{2}$ pala (72ml)
<b>Duration of treatment</b>	7 days	7 days
<b>Duration of study</b>	2 Months	2 Months
<b>Follow up</b>	1 <sup>st</sup> assessment: After 1 month 2 <sup>nd</sup> assessment: After 2 months	1 <sup>st</sup> assessment: After 1 month 2 <sup>nd</sup> assessment: After 2 months

**(a) INCLUSION CRITERIA:**

- Subjects aged between 21 to 35years.
- Subjects presenting the classical symptoms of *Artavakshaya*.
- Subjects presenting with symptoms of Oligomenorrhea.
- Spotting/ bleeding less than two days.
- Both married and unmarried women
- Subjects willing for *Basti karma*.

**(b) EXCLUSION CRITERIA:**

- Pregnant women
- Lactating women
- Haemoglobin less than 8g%.
- Subjects with other systemic illness

- Subjects with any ano-rectal complaints
- INVESTIGATION: 1) Hb%, 2) Thyroid profile, and 3) USG

**DIAGNOSTIC CRITERIA:**

- The pattern of uterine bleeding- bleeding occurring more than 35 days apart (*Yathochitakala adarshanam*)
- Lasting for less than 2 days (*alpa*)
- Scanty menstrual bleeding (*alpa*)
- Pain in vagina (*yoni vedana*)

**ASSESSMENT CRITERIA:**

- Duration of the menstrual cycle
- The interval between two cycles
- Pain during menstruation
- The number of pads used per day.

Table No. 2 – Showing Criteria for Assessment

Grading	The interval between two cycles	Duration of the menstrual cycle	Number of pads used per day	Pain during menstruation
0	28-32 days	4-7 days	3-4 pads/per day	No pain
1	32-36 days	3-4 days	2-3 pads/per day	Mild pain
2	37-41 days	2-3 days	1-2 pads/per day	Moderate pain
3	>41 days	1-2 days	Spotting	Severe pain
4	No menstruation			

**RESULTS**

**Table No. 3 – Effect of treatment on Interval between cycles within the group**

	<b>GROUP</b>	<b>N</b>	<b>MEAN RANK</b>	<b>S.O.R</b>	<b>Z value</b>	<b>p-Value</b>	<b>Inference</b>
BT	A	15	9.00	18.00	-	-	
	B	15	0.00	0.00	-	-	
AT	A	15	7.85	102.00	-2.474	0.013	Significant
	B	15	7.50	105.00	-3.494	0.000	Highly Significant
FU	A	15	8.12	105.50	-2.634	0.008	Significant
	B	15	8.00	120.00	-3.508	0.000	Highly Significant

When analyzing the interval between cycles within the group, Group A has shown a significant effect on the interval between the cycles reduced with a p-value <0.05, whereas Group B has shown a reduction with a Highly Significant effect with the p-value 0.000.

**Table No. 4 – Effect of treatment on Duration of Bleeding within the group**

	GROUP	N	MEAN RANK	S.O.R	Z value	p-Value	Inference
BT	A	15	7.50	15.00	-	-	-
	B	15	0.00	0.00	-	-	-
AT	A	15	3.50	21.00	-0.440	0.660	Not Significant
	B	15	5.00	45.00	-3.000	0.003	Significant
FU	A	15	6.00	66.00	-1.540	0.123	Not Significant
	B	15	0.00	66.00	-3.317	0.001	Significant

When analyzing the duration of bleeding within the group, Group A has not shown a significant effect statistically when comparing the p-value, but when comparing, the mean difference reduced to 4.00 which shows there was an improvement in the duration of bleeding, whereas Group B has shown Significant improvement with the increase of mean difference of 5.00 which means there was an increase in the duration of bleeding after treatment with the p-value <0.005.

**Table No. 5 – Effect of treatment on Pads used per day within the group.**

	GROUP	N	MEAN RANK	S.O.R	Z value	p-Value	Inference
BT	A	15	11.00	33.00	-	-	
	B	15	0.00	0.00	-	-	
AT	A	15	5.00	45.00	-0.494	0.621	Not Significant
	B	15	5.50	55.00	-3.051	0.002	Significant
FU	A	15	6.05	60.50	-1.105	0.269	Not Significant
	B	15	5.50	55.00	-3.051	0.002	Significant

When analyzing the effect of treatment on pads used per day within the group, Group A has not shown a Significant effect as the p-value was >0.05 but when comparing, the mean difference has shown a reduction of 6.00 which shows there was a significant improvement in pads used per day, whereas Group B has shown Significant improvement with the increase of mean difference of 5.50 which means there was an increase in usage of pads after treatment with the p-value <0.005.

**Table No. 6 – Effect of treatment on Pain during menstruation within the group**

	GROUP	N	MEAN RANK	S.O.R	Z value	p-Value	Inference
BT	A	15	8.50	17.00	-	-	
	B	15	0.00	0.00	-	-	
AT	A	15	4.00	28.00	-0.687	0.492	Not Significant
	B	15	2.50	10.00	-2.000	0.046	Significant
FU	A	15	4.00	28.00	-0.673	0.501	Not Significant
	B	15	3.00	15.00	-2.236	0.025	Significant

When analyzing the effect of treatment on pain during menstruation within the group, Group A has not shown a Significant effect as the p-value was >0.05 but when comparing the mean difference it has shown a difference of

4.50 after treatment which shows that group A had significant reduction in Pain during menstruation, whereas in Group B has shown Significant improvement with the increase of mean difference of 2.50 which means there was decrease pain after treatment with the p-value <0.05.

**Table No. 7 & 8 – Interval b/w two cycles between groups after treatment & follow-up.**

GROUPS	N	MR	SOR	U	z value	p-value
GROUP A	15	14.6	219	99	-0.633	0.526
GROUP B	15	16.4	246			

GROUPS	N	MR	SOR	U	z value	p-value
GROUP A	15	14.8	222	102	-0.490	0.624
GROUP B	15	16.2	243			

With respect to Interval b/w two cycles after treatment and at follow-up, there is no significant difference was noted because the p-value is > 0.05.

**Table No. 9 & 10 – Duration of bleeding between groups after treatment & follow-up.**

GROUPS	N	MR	SOR	U	z value	p-value
GROUP A	15	14.97	224.5	88.5	-1.197	0.231
GROUP B	15	16.03	240.5			

GROUPS	N	MR	SOR	U	z value	p-value
GROUP A	15	17.10	256.50	106.5	-0.275	0.783
GROUP B	15	13.90	208.50			

With respect to the Duration of bleeding after treatment and at follow-up, there is no significant difference was noted because the p-value is > 0.05.

**Table No. 11 & 12 – Pads used per day between groups after treatment and follow-up.**

GROUPS	N	MR	SOR	U	z value	p-value
GROUP A	15	17.1	256.5	88.5	-1.113	0.266
GROUP B	15	13.9	208.5			

GROUPS	N	MR	SOR	U	z value	p-value
GROUP A	15	16.33	245	100	-0.611	0.541
GROUP B	15	14.67	220			

With respect to Pads used per day after treatment and at follow-up, there is no significant difference was noted because the p-value is > 0.05.

**Table No. 13 & 14 – Pain during menstruation between groups after treatment & follow-up.**

GROUPS	N	MR	SOR	U	z value	p-value
GROUP A	15	17.77	266.5	78.5	-1.565	0.117
GROUP B	15	13.23	198.5			

GROUPS	N	MR	SOR	U	z value	p-value
GROUP A	15	17.83	267.5	77.5	-1.639	0.101
GROUP B	15	13.17	197.5			

With respect to Pain during menstruation after treatment and at follow-up, there is no significant difference was noted because the p value is > 0.05.

This implies that there was no difference in the effect of the treatment between the groups.

## DISCUSSION

### DISCUSSION ON DRUGS:

#### Probable mode of action of Arkapushpa taila according to Ayurvedic classics

Acharya Sushruta has advised Samshodhana and the use of Agneya dravyas in the management of 'Artavakshaya'. Acharya Kashyapa says Artava dushti is an Anuvasana yogya vyadhi. In this study 'Arkapushpa taila' is used for Matrabasti, which possesses 'Agneya' guna. To evaluate the mode of Action of 'Arkapushpa taila' the following points may be considered.

#### 'Arkapushpa taila' –

Artavakshaya can be principally because of the vitiation of Vata and Kapha doshas. As Arkapushpa possesses Ushna virya, Katu vipaka, and Vata-kaphahara property, it may act directly on this condition. Arkapushpa is a rich source of gallic acid, flavonoids, tannins, carbohydrates, and proteins. In an in vivo study of PCOS rats, the antioxidant property of gallic acid demonstrated an impact on the pituitary-ovarian axis, sex hormones, and oxidative stress. The presence of gallic acid in Arkapushpa can also have an impact on the HPO axis and decrease oxidative stress so it helps in proper menstruation. In a clinical report, it was demonstrated that ingestion of starch-rich dinners expands the amalgamation of Serotonin during the premenstrual stage. Thus, Arkapushpa taila matrabasti which is wealthy in carbohydrates will likewise expand the Serotonin levels. Subsequently, it very well may be added to the PMS condition. Tila Taila – Tila taila has Madhura rasa and vipaka, ushna virya, guru, snigdha, sukshma, vyavayi, sara and vikasi guna. It acts as vatahara, garbhashaya shodhana, shulahara and also acts as

Artava pravritti. Acharya Charaka explains it as Vataghnanam-uttamam, Pittala Na Shleshma-abhivardhanam. Acharya Sushruta explains as Yonishulaprashamana and Garbhashaya Shodhana property. As dravadravya is not mentioned, Tila taila is used in the preparation of Arkapushpa Taila. Both Arkapushpa and tila taila are having vatashamaka due to ushna virya and also do pitta vardhana and kapha shamaka action. Arkapushpa Taila also has Agneya guna along with Srotoshodhana property. These properties & the Matrabasti both do action on the regulation of vata dosha.

- **Shatapushpa taila (Anthem sowa)**
- It is anti-inflammatory, antihyperlipidemic, anti-hypercholesterolaemia, antioxidant, anti-spasmodic, emmenagogue, and carminative.
- It is Ritupravartini, yonisukra shodhani, anulomana property so can be given in Artavakshaya or Anartava.
- As it has Madhura rasa & ushna virya – vata shamaka.  
katu vipaka & ushna virya – kapha shamaka  
Together it is Vata-kapha shamana
- Also, it does Dhatukarma i.e Rasadhaturvardhaka/Raktadhatu vardhaka.
- Katu rasa & Ruksha-tikshna guna remove the obstruction in Srotas by Lekhana karma, along with it cures the Upalepa produced by Kapha in the Artavavaha srotas → Kapha vilayana helps in Srotoshodhana.
- With all these properties Shatapushpa is useful to regularize the function of the HPO axis and cure the Artavakshaya condition.

Parameter	Group A	Group B
Duration of bleeding	Agneya guna- along with vata-kaphahara action which does srotoshodhana, does pitakara action also, thus helping in improved artava pravritti.	Better results were seen in Group B. this may be because of its dual action of Artava janana and Rajorodha hara due to its ushna-tikshna guna.
The interval between two cycles	Laghu, Ushna and vata-kaphahara gunas help in removing the sanga in artavavaha srotases and vatanulomana. Thus, helping in removing the delay in the pravritti of Artava.	Katu-tikta rasa, ushna virya, katu vipaka → vatanulomana → srotoshodhana → artava pravritti.
Pain during menstruation	Vata shamaka, ushna virya, yonishulahara	Vata shamaka, yonishula hara

	Analgesic property.	Anti-spasmodic and anti-inflammatory.
Group B has shown better results than Group A because of its above properties.		

## DISCUSSION ON RESULTS

### Interval b/w two cycles

When analyzing the interval between cycles within the group, Group A has shown a significant effect on the interval between the cycles reduced with a p-value <0.05, whereas Group B has shown a reduction with a Highly Significant effect with the p-value 0.000. Hence in this parameter, both interventions are effective.

**GROUP A** – Mode of action – *Arkapushpa* has *Laghu, Ushna*, and *vata-kaphahara gunas* which help in removing the *Sanga* in *Artavavaha srotas* and does *Vatanulomana* action. Thus, helping in removing the delayed *Pravruti* of *Artava*.

**GROUP B** – Mode of action – *Shatapushpa* has *Katu-tikta rasa, ushna virya & katu vipaka* → *Kaphaharana* → *vatanulomana* → *srotoshodhana* → proper functioning of *Apana vata* → *Artava pravrutti*.

### Duration of bleeding

When analyzing the duration of bleeding within the group, Group A has not shown a significant effect statistically when comparing the p-value, but when comparing, the mean difference reduced to 4.00 which shows there was an improvement in the duration of bleeding, whereas Group B has shown significant improvement with the increase of mean difference of 5.00 which means there was an increase in the duration of bleeding after treatment with the p-value <0.005.

**GROUP A** – Mode of action – *Agneya guna* along with *vata-kaphahara* action which does *srotoshodhana*, does *pittakara* action also, thus helping in improved *Artava pravrutti*.

**GROUP B** – Mode of action – Better results were seen in Group B; this may be because of its dual action of *artava janana* and *Rajorodha hara* due to its

## OVERALL ASSESSMENT :

**Table No. 15 – Showing Overall assessment of the study.**

PARAMETERS	GROUP A	GROUP B	SIGNIFICANCE
Duration of bleeding	46.7%	40%	S
The interval between two	13.3%	60%	S

*ushna tikshna guna* in turn leading to *pittavardhana* → *artava utpatti & pravritti*.

### Pain during menstruation

When analyzing the effect of treatment on pain during menstruation within the group, Group A has not shown a significant effect as the p-value was >0.05 but when comparing the mean difference it has shown a difference of 4.50 after treatment which shows that Group A had significant reduction in pain during menstruation, whereas in Group B has shown significant improvement with the increase of mean difference of 2.50 which means there was decrease pain after treatment with the p-value <0.05.

**GROUP A** – Mode of action – *Vata dosha* is the causative factor for pain in the body. *Arkapushpa* has *madhura rasa, ushna virya, vatashamaka, yonishulaha*, analgesic properties, *basti karma*, and *sneha* which helps in reducing pain.

**GROUP B** – Mode of action – Because of *Vata shamaka, yonishula hara, and vatanulomana* properties and also has Anti-spasmodic and anti-inflammatory action of *shatapushpa* helped in reducing pain during menstruation.

### Between the Group –

With respect to Interval b/w two cycles, Duration of bleeding, pads used per day, and pain during menstruation after treatment and at follow-up, there is no significant difference was noted because the p-value is > 0.05.

### Overall assessment

In comparing the overall assessment Group, A has shown a 40% result whereas Group B has shown 58.35%. But when we compare, Group B had shown better results than Group A. The reason could be that *Katu rasa* and *Tikshna guna* help greatly in handling excessive *Kapha*.

<b>cycles</b>			
<b>Pain during menstruation</b>	40%	66.7%	NS
<b>Pads used per day</b>	60%	66.7%	S
<b>TOTAL</b>	40%	58.35%	

In comparing the overall assessment Group, A has shown a 40% result whereas Group B has shown 58.35%. But when we compare, Group B had shown better results than Group A.

## CONCLUSION

- *Artavakshaya* is quite common now a days because of their food habits, sedentary lifestyle, and stressful life. This can be correlated with Modern diseases i.e Oligomenorrhoea and Hypomenorrhoea. About 30% of women in their reproductive life suffer from irregular periods. Among these menstrual irregularities, Oligomenorrhoea accounts for 18.3%. In this study, a total of 30 subjects were registered 15 subjects in each group.
- Trial group (A) was administered with *Arkapushpa taila matrabasti* for 7 days and control group (B) was subjected to *Shatapushpa taila matrabasti*, the effect of which is already proven. *Arkapushpa taila matrabasti* has worked better in the subjects who had acute onset rather than a chronic condition.
- When we analysed the group, Group A showed significant results in the interval between the cycles whereas Group B has shown highly significant results in intervals between the cycles and significant results in the duration of bleeding, pads used per day, and pain during menstruation.
- When we compared the groups, no significant difference was seen in any of the parameters. Hence Null hypothesis ( $H_0$ ) is accepted.
- In comparing the overall assessment Group, A has shown a 40% result whereas Group B has shown 58.35%. But when we compare, Group B had shown better results than Group A. The reason could be that *Katu rasa* and *Tikshna guna* help greatly in handling excessive *Kapha*.
- A similar study has been conducted on *Artavakshaya* i.e Role of '*Krishna tila*'(orally) and '*Arkapushpa taila*' *Uttarabasti* in the management of *Artavakshaya* – the overall effect of therapies showed that *Arkapushpa taila Uttarabasti* with

*Krishna tila kwatha* (orally) is more effective to increase the duration of menstrual period, decrease in interval between two menstrual cycles and increase in the amount of menstrual blood.

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