



## AN OPEN LABEL, TWO ARM, RANDOMIZED CLINICAL STUDY ON EFFICACY OF PATHYAMALAKYADI KASHAYA AND DARVYADI KWATHA IN ASRIGDARA (DYSFUNCTIONAL UTERINE BLEEDING)

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### ABSTRACT

Dysfunctional uterine bleeding presents abnormal uterine bleeding without identifiable organic, systemic, or iatrogenic causes. It commonly results from anovulation due to dysfunction in the Hypothalamo pituitary ovarian axis. Asrigdara manifests as prolonged and excessive bleeding, including intermenstrual bleeding. The word "Asrigdara" explains about prolonged and excessive bleeding and bleeding during intermenstrual period. According to Caraka due to pradirana (excessive excretion) of raja (menstrual blood), it is named as pradara. Treatment traditionally involves shamana and shodana chikitsa to control bleeding. Pathyamalakyadi kashaya and Darvyadi kwatha, both possessing kashaya, tikta rasa, and sheeta veerya properties, were selected for comparison in this study for their potential hemostatic effects. The study aims to evaluate the efficacy of these formulations in managing Asrigdara.

**KEYWORDS:** Asrigadara; Pathyamalakyadi kashaya; Darvyadi kwatha; Dysfunctional uterine bleeding, pradara, menstrual blood, shamana, shodhana chikitsa.

### INTRODUCTION

Dysfunctional uterine bleeding is defined as a state of abnormal uterine bleeding without any clinically detectable organic, systemic and iatrogenic cause.<sup>[1]</sup> A normal menstruation denotes a healthy state of female reproductive system, if the menstrual bleeding is abnormally excessive, prolonged and is associated with pain, it indicates some underlying pathology. The severity of pathology may vary from simple hormonal imbalance to dreaded genital malignancy. The abnormal menstrual cycle not only disturbs the general health, it also disturbs routine work schedule of the woman and her entire family. In addition to this it also causes financial burden. The word "Asrigdara" explains about prolonged and excessive bleeding in Ayurvedic classics. According to Caraka due to pradirana (excessive excretion) of raja (menstrual blood), it is named as pradara and since, there is dirana (excessive excretion) of asrk (menstrual blood) hence, it is known as Asrigdara.<sup>[2]</sup> Various reports suggest that 30 to 50% of women in their reproductive age group suffer from excessive and irregular uterine bleeding by various causative factors. 28% of the female population consider their

menstruation excessive and will plan their social activities around their menstrual cycle, and nearly 10% of employed women will need to take time off from their work because of excessive menstrual loss.<sup>[3]</sup> 6 % of women aged between 25 to 44 years consult their General practitioner's about excessive menstrual loss every year.<sup>[4]</sup> Out of them 35 % referred to hospital.<sup>[5]</sup> 60 % will have a hysterectomy in the next 5 years.<sup>[6]</sup> Over 75000 hysterectomies are now carried out every year with 30 % of them carried out for menstrual disturbances alone.<sup>[7]</sup> If not treated earlier, Asrigdara leads to complications such as Dourbhalya, Brama, Murcha, Tama, Thrsna, Daha, Pralap, Pandu, Tandra and vataja rogas.<sup>[8]</sup> Asrigdara is a life threatening disease and should therefore be treated very seriously. The medical & surgical management of DUB in contemporary science fail to give satisfactory result and agonizes the patients with ill effects or adverse effects of treatment. Hence an effective management is the need of hour. Several formulations are mentioned in classical Ayurvedic text books for the management of Asrigdara.

In the light of above, it may be worthwhile to explore the potential of Pathyamalakyadi kashaya in the management of Asrigdara. Thus the present study is being undertaken to scientifically study and validate the effect of Pathyamalakyadi Kashaya.<sup>[9]</sup> in the management of Asrigdara. As Pathyamalakyadi kashaya is having Tikta Kashaya rasa, Sheethoushna virya and is said to be having Kapha Pitta and vatahara and Vedanasthapana, Stambhana action. In previous work done, it is proved that Darvyadi kwatha in management of Asrigdara has given result ( $P < 0.001$ ) significantly.<sup>[10]</sup> Hence Pathyamalakyadi Kwatha is selected for the present study to prove effective in comparative with Darvyadikwatha.

### OBJECTIVES

1. To evaluate the effect of Pathyamalakyadi kashaya in the management of Asrigdara.
2. To evaluate the effect of Pathyamalakyadi kashaya in comparatively with Darvyadi kwatha in the management of Asrigdara.

### MATERIALS AND METHODS

#### Source of data

Samples for the study was taken from OPD and IPD, Department of of prasutitantra and stri roga Shri Dharamsthala Manjunatheshwara College of Ayurveda and Hospital, Hassan.

#### Method of collection of data

##### Plan of study

An open label, two arm randomized clinical study. 44 patients, fulfilling the inclusive criteria and exclusive criteria were selected. A detailed case proforma was prepared considering all points of history taking, physical examination, lab investigation. The parameters of signs & symptoms, before treatment & after treatment were scored and analyzed on the basis of standard method of statistical analysis.

groups	Pathyamalakyadi kashaya	Darvyadi kwatha
subjects	20	20
dosage	30 ml twice daily before food	30 ml twice daily before food
anupama	Sukhoshna jala	Sukhoshna jala
Duration	60 days	60 days
Follow up	The subjects were followed up for once in 15 days during the course of treatment	The subjects were followed up for once in 15 days during the course of treatment

### ASSESSMENT CRITERIA

- The effect of therapies was assessed before and after treatment on the basis of subjective criteria:
- Interval between cycles
- Duration of bleeding
- Amount of bleeding
- Consistency of bleeding- Presence of clots
- Colour of bleeding
- Intermenstrual bleeding
- Pain abdomen during menstruation

### DIAGNOSTIC CRITERIA

- Diagnosis was made on the basis of symptoms of Asrigdara.
- Menstrual bleeding more than 5 days.
- Patient using more than completely soaked 3 pads per day (Patients were instructed to use pads of same company).
- Inter menstrual bleeding less than 21 days atleast for 2 cycles.
- Irrespective of parity

### INCLUSION CRITERIA

- Patients aged between 16-50 years.
- Patients ready to sign the informed consent form.
- Patients presenting with excessive, prolonged menstrual bleeding, intermenstrual bleeding at least for two months

### EXCLUSION CRITERIA

- Uterine polyp/Endometrial poly/endo cervical polyp.
- Carcinoma of cervix.
- Patient using intrauterine contraceptive device.
- Coagulation disorders.
- Thyroid problems
- Ischemic heart disease.
- Threatened, spontaneous or incomplete abortion / Ectopic pregnancy.
- Diabetes Mellitus/Tuberculosis/Renal failure
- Patients with uterine and pelvic pathology. (Fibroid, Adenomyosis)
- Benign and Malignant growth.

### Associated Symptoms

- Lowbackache
- General Weakness
- Giddiness

### Interval between cycles

- Grade 1 15-20 days
- Grade 2 21-30 days
- Grade 3 31-40 days
- Grade 4 >40 days

**Amount of bleeding**

- Grade 0 1-2 pads / day
- Grade 1 3-4 pads/day
- Grade 2 5-6 pads/day
- Grade 3 7&>7 pads/day

**Duration of flow**

- Grade 0 3-5 days (normal)
- Grade 1 5-7 days (mild)
- Grade 2 7-10 days (moderate)
- Grade 3 10-15 days (severe) and more than 15 days

**Consistency of bleeding**

- Grade 0 Absent
- Grade 1 Mild(2-3 clots per day)
- Grade 2 Moderate(4-5 clots per day)
- Grade 3 Severe(>5 clots per day)

**Pain abdomen**

- Grade 0 No pain
- Grade 1 Mild
- Grade 2 Moderate
- Grade 3 Severe

**Lowbackache**

- Grade 0 No pain
- Grade 1 Mild
- Grade 2 Moderate
- Grade 3 Severe

**General Weakness**

- Grade 0 No pain
- Grade 1 Mild
- Grade 2 Moderate
- Grade 3 Severe

**Giddiness**

- Grade 0 No pain
- Grade 1 Mild
- Grade 2 Moderate
- Grade 3 Severe

**STATISTICAL ANALYSIS**

Statistical analysis was done with SPSS, Version 23

**Within the group analysis**

Since the data was Ordinal, Friedman test was applied as a primary test followed by Bonferroni correction. As a post-hoc test, Wilcoxon signed rank test was applied for symptoms which showed significance in Friedman test, for interpreting the time of significant change in symptoms.

**Between the group analysis**

As the data was Ordinal, Mann-Whitney U test was applied to compare the data, between the groups.

**Sample size estimation**

Number of population:- 40

Alpha level:- 0.05

Confidence interval:- 95%

According to the Yamane equation

$$n = N / (1 + Ne^2)$$

Where, N = Population size, e = alpha level e = 0.05 if the confidence interval is 95%.

Calculation,

$$\text{Sample size } (n) = 40 / (1 + 40(0.05)^2) = 36.36$$

Hence required sample is 36

**RESULTS**

The comparative study aimed to assess the efficacy of Pathyamalakyadi Kashaya and Darvyadi Kwatha in managing Asrigdara, focusing on various parameters including interval between cycles, duration and amount of bleeding, presence of clots, pain abdomen during menstruation, as well as symptoms of generalized weakness, low backache, and giddiness. The findings are discussed below:

**Interval Between Cycles**

Both Pathyamalakyadi Kashaya and Darvyadi Kwatha exhibited significant improvements in the interval between menstrual cycles. Statistical analyses, encompassing the Friedman test and Wilcoxon signed-rank test, demonstrated noteworthy reductions in cycle intervals for both treatments compared to baseline. Pathyamalakyadi Kashaya demonstrated effectiveness across various follow-up periods, showing statistically significant improvements from pre-treatment to post-treatment stages. Similarly, Darvyadi Kwatha exhibited significant enhancements during these intervals, indicating its efficacy in managing Asrigdara.

**Duration of Bleeding**

Both treatments showed effectiveness in reducing the duration of menstrual bleeding. Statistical analyses revealed significant reductions in bleeding duration for both groups compared to baseline. Pathyamalakyadi Kashaya demonstrated notable improvements across various follow-up periods, including from pre-treatment to post-treatment stages. Similarly, Darvyadi Kwatha exhibited significant improvements during these intervals, indicating its efficacy in managing bleeding duration in Asrigdara patients.

**Amount of Bleeding**

Pathyamalakyadi Kashaya and Darvyadi Kwatha were both effective in reducing the amount of menstrual bleeding. Statistical analyses indicated significant reductions in bleeding amount for both treatments compared to baseline. Pathyamalakyadi Kashaya showed significant improvements particularly from pre-treatment to post-treatment stages. Similarly, Darvyadi Kwatha exhibited significant improvements during these intervals, indicating its efficacy in managing bleeding amount in Asrigdara patients.

### Presence of Clots

Both treatments demonstrated effectiveness in reducing the presence of clots during menstruation. Statistical analyses revealed significant reductions in clot presence for both groups compared to baseline. Pathyamalakyadi Kashaya showed significant improvements particularly from pre-treatment to post-treatment stages. Similarly, Darvyadi Kwatha exhibited significant improvements during these intervals, indicating its efficacy in managing clot presence in Asrigdara patients.

### Pain Abdomen

Both Pathyamalakyadi Kashaya and Darvyadi Kwatha effectively reduced abdominal pain during menstruation. Statistical analyses demonstrated significant reductions in pain abdomen for both treatments compared to baseline. Pathyamalakyadi Kashaya exhibited significant improvements particularly from pre-treatment to post-treatment stages. Similarly, Darvyadi Kwatha exhibited significant improvements during these intervals, indicating its efficacy in managing pain abdomen in Asrigdara patients.

### Generalized Weakness, Low Backache, and Giddiness

Both treatments exhibited significant improvement in generalized weakness, low backache, and giddiness. Statistical analyses revealed significant reductions in these symptoms for both groups compared to baseline. Pathyamalakyadi Kashaya and Darvyadi Kwatha demonstrated effectiveness across various follow-up periods, indicating their efficacy in managing these symptoms in Asrigdara patients.

### DISCUSSION

The probable mode of action of the drugs in this study is elucidated based on the principles outlined by Acharya Charaka, which emphasize the importance of five properties - rasa, guna, veerya, vipaka, and karma. The study focuses on drugs with tikta rasa and kashaya as predominant rasas, laghu and ruksha gunas, sheeta and ushna veerya, and katu vipaka.

#### 1. **Rasa:**

- **Tikta Rasa:** These drugs possess tikta rasa, which aids in ama pachana by enhancing agni. Additionally,

tikta rasa helps in sroto shodhana, particularly targeting the raktavaha srotas, leading to rakta shodhana. Thus, its properties include deepana (enhancing appetite), pachana (digestive), raktaprasadana (blood purification), daha-prashmana (alleviating burning sensation), and shoshana (drying).

- **Kashaya Rasa:** Predominant in prithvi, kashaya rasa exhibits stambhana action, crucial for conditions like "Asrigdara" characterized by excessive bleeding. Its properties involve stambhana (astringent), rakta-pitta prashmana (pacifying bleeding disorders), and shoshana (drying).

#### 2. **Guna:**

- In Asrigdara, there is an increase in drava pitta containing teja and jala mahabhuta. The drugs contain laghu and ruksha gunas, aiding in the shoshana (drying) of increased jala mahabhuta. Additionally, they act as kapha-pitta shamaka (pacifying kapha and pitta doshas).

#### 3. **Veerya:**

- The drugs exhibit sheeta and ushna veerya. Sheeta veerya possesses pitta shamaka (pacifying pitta) and rakta stambhaka (arresting bleeding) properties, directly acting on teja and jalamahabhuta, resulting in raktapittahara (pacifying bleeding disorders).

#### 4. **Vipaka:**

- The vipaka of these drugs is katu, which is laghu and acts as a kaphagna (alleviating kapha).

#### 5. **Karma:**

- Pathyamalakyadi kashaya and Darvyadi kwatha act according to vyadhi pratyaneeka chikitsa, addressing the specific pathology of the disease. Their actions include deepana (enhancing digestive fire), pachana (digestive), rakta shodhaka (blood purifier), rakta stambhaka (arresting bleeding), vranaropaka (healing wounds), balya (strengthening), shothahara (anti-inflammatory), raktapittahara (pacifying bleeding disorders), garbhashaya sankochaka (contracting the uterus), and rasayana (rejuvenating). They also regulate the normal function of apanavata, thus their efficacy is well-suited for the treatment of "Asrigdara".

### Modern action of pathyamalakyadi kashaya and Darvyadi kwatha

<i>Pathyamalakyadikashaya</i>	<i>Darvyadikwatha</i>
<i>Amalaki, haritaki</i> and <i>vibhitaki</i> possess analgesics – reduces the pain abdomen and low backache.	<i>Daruharidra</i> contains berberine and isoquinoline alkaloids. Posses analgesic properties
<i>Shunti</i> and <i>haridra</i> – possess anti-oxidant properties.	<i>Rasanjana</i> – Rejuvenative property Vasicine - uterotonic activity different species in animals in vivowas similar to that of oxytocin and methylergometrine, Vasicine also potentiated prostaglandin- induced uterine contractions in rats.
<i>Devadaru</i> having anti-spasmodic properties inturn reduces the pain.	<i>Musta</i> -improves the uterumuscular activity and does vasoconstriction
<i>Lodhra</i> - possess vasoconstrictiveaction. And anti- fibrinolytic activity.	<i>Bhallataka</i> – analgesic property.
<i>Lodhra</i> –posses Ethanollic extract from bark acts as analgesics.	<i>Bilwa</i> antispasmodic, analgesics, <i>Kiratatikta</i> -analgesic, antispasmodic properties

**CONCLUSION**

The efficacy of Pathyamalakyadi Kashaya and Darvyadi Kwatha in managing these symptoms may be attributed to their properties such as rasayana (rejuvenating), vatahara (alleviating vata dosha), shoolahara (pain-relieving), and sheeta guna (cooling properties).

The mode of action of Pathyamalakyadi Kashaya involves its ingredients possessing Vata and Pitta shamaka properties, which help in reducing the flow of menstruation. Similarly, Darvyadi Kwatha acts by reducing the saraguna of Pitta, thereby reducing the flow of menstruation.

In conclusion, both Pathyamalakyadi Kashaya and Darvyadi Kwatha demonstrated significant efficacy in managing various symptoms associated with Asrigdara, including interval between cycles, duration and amount of bleeding, presence of clots, and pain abdomen during menstruation. These findings suggest that both formulations could be considered effective options for the management of Asrigdara in clinical practice.

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