# Pharmacontrol Research

### WORLD JOURNAL OF PHARMACEUTICAL RESEARCH

SJIF Impact Factor 8.084

Volume 10, Issue 12, 1634-1646.

Research Article

ISSN 2277-7105

## A CLINICAL STUDY OF PHALTRIKADI KWATH ORALLY AND BALA TAIL NASYA ON ASRIGDARA W.S.R TO DYSFUNCTIONAL UTERINE BLEEDING

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Article Received on 09 August 2021,

Revised on 29 August 2021, Accepted on 19 Sept. 2021,

DOI: 10.20959/wjpr202112-21776

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#### **ABSTRACT**

With advancements and modernization of current era, incidence of Abnormal uterine bleeding are encountered by women throughout the Globe and India is no exception to this. According to Ayurvedic classics the word *Asrigdara/Pradara* means untimely flow of blood in respect of amount and duration. *Asrigdara* can be correlated with abnormal uterine bleeding specially, dysfunctional uterine bleeding (DUB) in modern literature. The aim of the present study was to evaluate "The effect of *Phaltrikadi Kwath* orally and *Bala Taila Nasya* on *Asrigdara*". Materials and Methods: A total of 30 patients were selected for the present research work and randomly divided into two groups of 15 patients each. In Group A, patients were treated with *Phaltrikadi Kwath* orally in a dose of 40ml orally two times in a day

with *Madhu* before meal, for 7 days and 8 drops of *Nasya* in each nostril for 5 days after cessation of the menstrual cycle, while in Group B, patients were given *Phaltrikadi Kwath* 

orally in a dose of 40ml orally two times in a day with *Madhu* before meal, for 7 days and *Pathya* for 30 days. After conducting the clinical trial on 30 patients, the data was obtained and analysed statistically. **Results:** It was observed that both the groups were effective in ameliorating the symptoms of *Asrigdara*. However, on comparison of both Groups A and B, Group A showed better results with minimal reoccurrence in symptoms. **Conclusion:** It showed that the specific therapy (Nasya karma with Bala Tail) along with oral administration of *Phaltrikadi Kwath* was more effective in the treatment of *Asrigdara*, in comparison to *Phaltrikadi Kwath* alone.

**KEYWORDS:** Asrigdara, dysfunctional uterine bleeding, Nasya Karma, Bala Tail.

#### INTRODUCTION

Women play a pivotal role in building a healthy society and women's health is of particular concern due to widespread discrimination against women in the world and leaving them in disadvantage. Abnormal uterine bleeding is a wide spread symptom that effects not only the health of women but also result in loss of work. *Ayurveda*, the traditional system of medicine believes that menstrual cycle is a major health indicator during the reproductive life of women.

In the present era, changing role of women in society, nutritional standards, racial factors, environmental influences, inflexible work schedules have added stress to women and they are likely to avoid important aspects of self-care. As a result, there is increase in duration as well as frequency of menstruation.

According to classics menstrual blood flow is considered normal if it occurs in cyclic fashion and in required amount and duration but when there is untimely flow of blood in respect of amount and duration it is termed as *Asrigdara*, [1]/ *Pradara*, [2] in ayurvedic texts. According to the Ayurvedic classics the menstrual cycle depends upon *Tridosha*, *Panchamahabuth* and *Saptadhatu* theory. On the basis of description in literature given by different *Ayurved Acharyas*, *Asrigdara* can be correlated with Abnormal uterine bleeding. This study is confined to Dysfunctional uterine bleeding only. Regular cyclic menstruation results the choreographed relationship between the endometrium and its regulating factors. Any type of disturbance between the regulatory mechanism of hypothalmo-pituitary-ovarian. [3,4] (H-P-O) axis or pelvic diseases results in abnormal uterine bleeding. DUB is one of the most common causes of abnormal uterine bleeding seen mostly in post-menarche and pre-menopausal ages.

Currently, DUB is defined as a state of abnormal uterine bleeding with excessive, prolonged and irregular bleeding of the endometrium frequency <21 days; duration >7 days; daily use of sanitary towels/tampons >1 per hour or two, that does not cause pain and does not have any organic cause. Menorrhagia accounts for one of the most common causes of iron deficiency anaemia in females after nutritional anaemia. Many women seek late medical advice, delay its treatment and ultimately land on chronic ill health due to excessive blood loss and anaemia.

Though modern science has given various therapeutic options to deal with this problem i.e. medical<sup>[7]</sup> (hormonal and/or non-hormonal) and surgical.<sup>[8,9,10,11,12]</sup> (D&C, endometrial ablation, hysterectomy) but no treatment is free of side effects like headache, GIT disturbances, weight gain etc. Despite considerable progress in the past decades, society continued to fail to meet the health care which is the need of women at key moments of their lives, particularly in their adolescent and in spite of that the incidence rate of *Asrigdara* is increasing.

#### MATERIALS AND METHODS

Materials and Methods were discussed under following headings.

#### Criteria for the Selection of Drugs

Disease Asrigdara is having Pitta and Rakta Dushti with Apan Vayu Vaigunya. [13] Function of Agni is also impaired in Asrigdara. Due to impairment of Agni, Rasa Dhatu didn't formed properly and Artava (Updhatu of Rasa) [14] formation is also impaired. So according to its pathogenesis (Samprapti) Pittashamaka, Vatanulomana, Rakta-sthapaka, Rakta-samgrahi, Agni-deepana and Garbhashaya-balya Chikitsa is beneficial in Asrigdara. [15] Variety of treatment options are there in the management of Asrigdara, including Shodhana. [16] (Virechana, Basti both Niruha and Anuwasana basti, Asthapana Basti followed by Uttarabasti and Nasya is beneficial) and Shamana Chikitsa (Rakta Samgrahana, Rakta Sthaapana and Tikta Rasa Dravyas). [17] Keeping these properties in mind, Bala taila nasya is taken due to its Vatashamaka property and is good nervine drug whereas good alternative to hormonal therapy along with this it is helpful in managing Pradara, Garbhashaya Daurbalya and Yonirogas. Phaltrikadi Kwath, [18] (Haritaki, Vibhitaki, Amalaki, Vasa, Vacha, Devdaru, Durva, Samanga, Prishnaparni and Lajja) was chosen because of maximum ingredients have properties of pacifying Pitta and Kapha Dosha by their Tikta Rasa, Sheeta Veerya.

#### **Selection and Grouping of Patients**

This study was conducted at the P.G Department of *Prasuti Tantra Stri Roga* of Dr. S. R. Rajasthan Ayurved University Jodhpur. Thirty clinically diagnosed and confirmed patients with *Pratyatma lakshanas* of *Asrigdara* from OPD & IPD were registered for the present clinical trial and were randomly divided into two groups.

**Group-A** study was completed on 15 clinically diagnosed patients of *Asrigdara* with *Phaltrikadi Kwath* 40 ml/BD with *Madhu* as *Anupana* before meal for seven days (D1-D7) for three consecutive cycles and *Bala Tail Nasya* 8 drops in each nostril for 5 days for three consecutive cycles after cessation of menses.

**Group-B** study was completed on 15 clinically diagnosed patients of *Asrigdara* with *Phaltrikadi Kwath* 40 ml/BD with *Madhu* as *Anupana* before meal for seven days (D1-D7) for three consecutive cycles. Along with intake of above drug, patients were advised to take fruits, green vegetables, simple foods, to take rest, do Pranayama for ten minutes and avoid spicy food, fried food, fermented food, non-vegetarian food, avoid heavy weight lifting, journey, heavy strenuous work, tension and avoid sleeping in day time in and around menstruation. Follow up of the patient after first, second and third month for assessment in amount, duration, color, and consistency of menstrual blood and relief in pain in the abdomen during menses were noted.

#### **Inclusion Criteria & Exclusion Criteria**

Patients between menarche to menopause willing for the trial and with history of excessive bleeding from at least 2 consecutive cycles, with clinical features along with *Pratyatma lakshanas* of *Asrigdara* whereas, patients diagnosed as DUB as per USG were included in the study. Were included in the study. Patient not willing for trial, having bleeding sites other than uterus, with uterine, pelvic pathology like fibroid, adenomyosis, PID Endometrial, endocervical polyp and carcinoma cervix, uterus etc., Hb<7gm percentage and bleeding due to coagulation disorders, women using IUCD, OCPs, patients having any allergy to the drugs were excluded from the study.

#### **Investigations**

USG- Abdomen & pelvis, Veneral disease research, BT, CT, Human immunodeficiency virus, Hepatitis B surface antigen test, thyroid function test were carried out before treatment to rule out any other pathological conditions whereas complete blood count, ESR were

Oestradiol was only for Group A (BT and AT). Cases were followed up at every one month interval for three consecutive cycles during the trial to find the effect of drug and procedure on the subjective parameters and up to one cycle after completion of the trial. Laboratory investigations were carried out after the completion of trial in order to assess the effect of drug on the objective parameters.

A total of 30 patients were selected for the present study and scoring was done.

#### **Scoring**

Scoring was done entirely on the basis of patients' statement. For assessment of the amount of blood loss, the cases were advised to use standard size diapers or sanitary pads and asked to remove diaper only when it was properly soaked and count the pads used per day during menstruation. Scoring was done after analysing the parameters [Tables 1].

PARAMETERS-	Criteria	Score Intensity of menstrual blood
1	l-2 completely soaked pad/	day 0
3 –	4 completely soaked pad/da	y 1
4-5	completely soaked pad/day	2
	>5 completely soaked pa	d/day 3
Amount of flow	Moderate (without clots)	0
	Moderate (with clots)	1
	Heavy (without clots)	2
	Heavy (with clots)	3
Duration of Menstrual Period	Up to 5 days	0
	6-7 days	1
	8-9 days	2
	More than 9 days	
Interval between Menstrual Perio		0
	20 to 24 days	1
	15 to 19 days	2
	< 15 days/irregular	3
Body ache	Occasional on doing	heavy work 0
	After doing extra work	1
	After doing routine wor	
	Even doing rest	3
Burning Sensation	No burning	0
	Occasional mild burnin	0
	Often mild burning	2
	Severe burning	3
Pain during Menstruation	No pain	0
	Mild pain, women compl	
	but do not require any dru	
	Moderate pain, women con	
	takes one or two doses of d	•
	Pain does not affect routine	
	Severe pain, women compl	
	takes 3- 4 doses of drug or	•
	influences general activity.	. 3

#### **Final Assessment of Result**

Result was done based on the subjective and objective parameters.

- 1. Complete remission:- Patients showing more than 90% relief in intensity, duration, intermenstrual period, relief of pain and associated symptoms.
- 2. Cured:- Patients showing 75%-89% relief in intensity, duration, intermenstrual period, relief of pain and associated symptoms.
- **3.** Markedly improved: Patients showing 50%-74% relief in above mentioned symptoms.
- **4. Partially improved**:- Patients showing 25% 49% of relief in symptoms.
- **5. Unimproved** Patients showing less than 24% of relief in symptoms.

#### **RESULTS AND DISCUSSION**

The present clinical study was taken up in the background of wide spread prevalence and growing incidence of disease throughout the globe and inadequacy of safe drugs in the modern system and increasing focus on alternative systems.

The review of literature shows that *Artava* flows out from the Yoni with the help of proper functioning of Apana (Pravritti) and Vyana (blood circulation) Vayu after attaining a particular age at a specific time in cyclic fashion. It is said that mainly the menstrual rhythm i.e. length of the cycle depends upon the hypothalamo- pituitary- ovarian function and amount of blood loss depends upon the uterine condition.

Altered normal cycle of menstrual in terms of increase in number of days or frequency is DUB. Vata and Pitta Doshas are the major ones in initiating the Samprapti of Asrigdara.

Nasa being the gateway to Shira (head), the drug administered through nostrils, reaches Shringataka (a Sira Marma by Nasa Srota and spreads in the Murdha (Brain). [19,20,21] and scratches the morbid doshas from supra clavicular region completely (A.S. Su.29/3). Modern science also says that the nasal cavity provides unique access to the brain as it is the only accessible surface of the body with direct innervation to the central compartment, In superior part of nasal cavity – (inferior part of cribriform plate) – olfactory epithelium (10-100 million receptors for smell) Olfactory receptors bundle of axons collectively from olfactory nerve nerve – terminates in paired masses of grey matter called olfactory bulb – limbic system – hypothalamus – pituitary.

With the above frame in mind Bala Taila Nasya and Phaltrikadi Kwath was selected.

#### Intensity of menstrual blood

Maximum 15(50%) patients were of 21-25 pads, 09(30%) patients of 25pads, 04 (13.33%) patients were of less than 15 pads and 2(6.66%) patients were of 15-20 pads. As it is said in the literature that in normal menstruation fading corpus luteum from previous cycle allows increase in FSH during the follicular phase, which in turn, cause increasing levels of oestrogen from the granulosa cells and result in uterine endometrial proliferation, and after sufficient rise in oestrogen levels provide negative feedback on pituitary FSH secretion and then there is increase in LH levels which modulate the secretion of progesterone. Oestrogen is a principal hormone which is effective on endometrial glands and vasculature, progesterone mainly affects the stroma. Where prolonged hypoestrogenism unopposed by progesterone leads to proliferative endometrium and hyperplasia with poor stromal matrix as spiral arterioles are often suppressed and venous capillaries are dilated and increase in number. Maximum percentage of relief i.e. 77.77% in Group A which was statistically extremely significant (P <0.001), followed by Group B in which percentage of relief was, 64.28% which was statistically very significant (P<0.01). From the study, it has been observed that adolescence patient being registered under Group A has shown significant result in reducing the intensity of menstrual blood as in those patients it was seen that there is increase in quantity of FSH formation after Nasya, which has led in opposing the prolonged hypoestrogenism, whereas in premenopausal patient, it has been observed that there is decrease in extra increased FSH levels along with an improvement in quantity also. As maximum ingredients of Phaltrikadi kwath have Raktapittahar properties whereas Bala Tail Nasya have helped in maintaining the required quantity of FSH levels according to particular age group. On the other hand Group B patients have shown results but less in comparison to Group A.

#### **Amount of bleeding**

Data shows about 12(40%) patients had heavy bleeding without clots during menses and 09(30%) patients had moderate bleeding with clots during menses, 09(30%) patients had heavy bleeding with clots and no patients were registered with moderate without clots. Maximum percentage of relief i.e. 71.87% in Group A which is statistically significant (P<0.001), followed by Group B in which percentage of relief was, 57.15% which was statistically significant (P<0.001). Results on amount of bleeding was more in Group A. Increasing levels of oestrogen from the granulosa cells result in uterine endometrial proliferation and as literature says that amount of blood depends on uterine conditions. Most

of the components of used *Phaltrikadi kwath* have *Tikta* and *Kashaya Rasa*. These *Rasas* by their *Samgrahi* and *Stambhaka* property help in *ShleshmaRakta-Pitta Prashamana* and *Raktasangrahana*. It will helps in *Shodhana* of *Dushita Pitta* and *Rakta*. On the other hand it was observed that there is increase in FSH levels which has further led to decrease in levels of oestrogens, as fall in oestrogen levels cause decrease in endometrial proliferation. In this study the base levels of the hormones were taken into consideration. The decrease in the oestrogen level give the positive feedback to FSH and in turn the FSH increase in mid cycle may lead to production of LH and this maintains the menstrual cycle.

#### Interval between menstrual period

Data signifies that maximum 15(50%) patients had interval of 20-24 days between two cycles, 09 (30%) patients had interval of 25-28 days, 04 (13.33%) patients had interval of less than 15days between two cycles & 02(6.66%) patients had interval of 15-19 days. Maximum percentage of relief i.e., 88.26% in Group A which was statistically extremely significant (P <0.001), followed by Group B in which percentage of relief was, 71.43% which was statistically very significant (P <0.01). Group A has shown maximum effect on inter menstrual period. As said above, rhythm of cycle is under the control of H-P-O axis. It was seen that in Group A patients who were registered with decreased inter menstrual period, few of them were found to have increased FSH levels which signifies that their high levels of FSH have resulted in short follicular phase and ultimately decrease in inter menstrual period. After *Nasya*, it was seen that their menstrual cycle went to normal as by *Bala Tail Nasya* there was decrease in vitiated *Vata Dosha*.

#### Days of menstruation

Data shows that maximum 14(46.00%) patients had 6-7 days of duration of bleeding, 06(20%) patients had 8-9 days and 04(13.33%) patients had duration of more than 9 days, 6(20%) patients had up to 5 days of bleeding. Maximum percentage of relief i.e. 81.22% in Group A which was statistically very significant (P <0.01). The relative relief in Group B is less at 68.16% which was statistically extremely significant (P <0.001). Group A has shown maximum effect on duration of bleeding. Ingredients of formulation used in the treatment of *Asrigdara* are mainly rich in *Kashaya Rasa* and *Tikta Rasa* because both of these *Rasa* have the property of astringent i.e. *Stambhana Guna* in *Ayurveda* and thus due to astringent property, bleeding will be checked. Whereas *Phaltrikadi kwath* have *Shothahara*, *Ropana* and *Vedanasthapana* action which help in *Srotoshodhana* and *Garbhashaya Shodhana* 

thereby reducing inflammation and uterine congestion. Presence of *Sandhaniya* and *Vrana-ropana* drugs, reduce the fragility of endometrial capillaries and thus helps in their toning.

#### **Burning sensation**

Maximum percentage of relief i.e.66.67% in Group A which was statistically significant (P<0.05), followed by Group B in which percentage of relief was, 57.87% which was statistically very significant (P <0.01). Group A has shown maximum relief in burning sensation. Most of the components of *Phaltrikadi kwath* have *Sheeta Veerya*. *Sheeta Veerya* does *Pittashamana*, *Rakta-samgrahana* / *Rakta-stambhana* and *Dahaprasamana*, that corrects burning sensation and excessive blood loss.

#### **Body ache**

As for Body ache, maximum percentage of relief i.e. 68.40% was noticed in Group A which was statistically extremely significant (P <0.001). On the contrar, Group B noticed 54.16 percent of relief which was statistically extremely significant (P <0.001). Improvement was more in Group A than Group B. In Group A, *Bala Tail Nasya* may have helped in settling down the vitiated *Vata Dosha* as it is the cause for pain and when added with drugs of *Kwath* which have *Vednasthapan* properties. Moreover, it can attributed to the action of reducing *Vata Dosha* by *Bala Taila Nasya* along with the action of *Vednasthapan* by *Phaltrikadi kwath* may have resulted in reducing body ache. It has been observed that in Group A there is slight increase in Hb levels as decrease Hb levels lead to body ache. As a result, relief in body ache is more in Group A as compare to Group B.

#### Pain during menses

Maximum percentage of relief in pain (46.15 per cent) during menses is noticed in Group A which was statistically significant (P<0.05) and slightly less in Group B 43.73% which was statistically significant (P<0.05). Group A has shown maximum relief in pain during menses. Normally DUB is pain less but sometimes due to myometrial contractions in order to expel sloughed endometrial tissue from uterus there is decrease in local uterine ischemia which may result in pain during menses. In Group A, *Bala Tail Nasya* has helped in normalising the vitiated *Vata Dosha* and ingredients of *Phaltrikadi kwath* have properties which help in *Vednasthapana*, *Garbhashayashothahara*, *Shotha-Vedanayuktavikara*, *Garbhashaya-Daurbalya*. Most of the ingredients of *Phaltrikadi kwath* have *Tikta* and *Kashaya Rasa* which thereby help in *Ama- pachana* and *Dosha-pachana*. Smooth muscle relaxant and antispasmodic properties of drugs reduces the contraction of myometrium, thus reduces blood

loss, antioxidant, anti-inflammatory, haemostatic, altering and intellect promoting. Drug having anti-inflammatory property which may help in reducing the prostaglandin levels thus reducing the menstrual blood loss, dysmenorrhoea as well as pelvic congestion which is the main factor of the pathogenesis of the disease.

#### **Intra Group Comparision**

**Group A** Extremely significant results are shown on Intensity of menstrual blood, Amount of flow, Inter menstrual period and Body ache. Results on Burning sensation and Duration of menses were very significant whereas result in Pain during menses was significant.

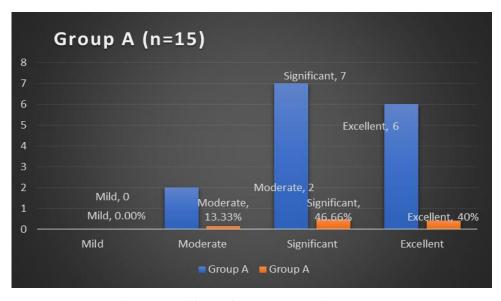
Very significant results are shown in platelet, ESR, while significant results are shown in oestradiol, whereas result in TLC count was not quite significant. Results on Hb, FSH and LH were Non-significant.

**Group B** Extremely significant results are shown on Amount of menstrual blood, Duration, and body ache. Results on Intensity, intermenstrual period were very significant and on pain during menses were significant. Very significant results was shown in ESR, while not quite significant results was shown TLC. Results on Hb and platelet were Non-significant.

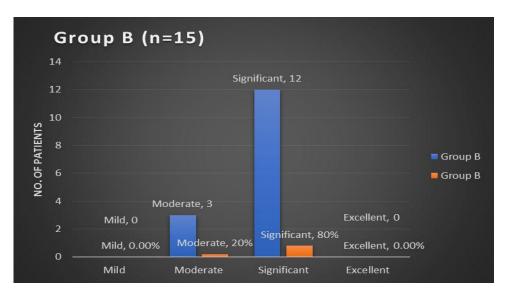
#### **Inter Group Comparision**

Non-significant results were obtained in subjective and objective parameters in both groups.

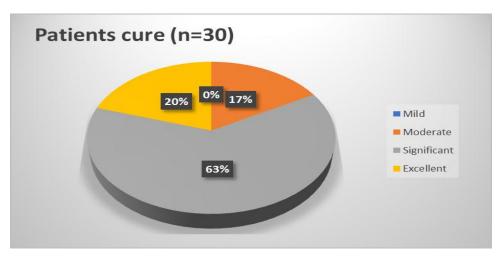
Comparing the symptomatic improvement in both groups it was found that overall relief was higher in Group A followed by Group B i.e. 06(40%) patients having excellent relief, 07(46.66%) patients showed significant relief, 02(13.33%) patient showed moderate relief and 00(0.00%) patient showed mild relief. In Group B 00(0.00%) patient showed excellent relief, 12(80.00%) patients showed significant relief, 03(20.00%) patients showed moderate relief. So the effect of therapy/ drug was more in Group A in comparison to Group B. Comparing the symptomatic improvement in both groups it was found that Average percentage of relief was higher and patients had minimal reoccurrence of symptoms in 'Group A' i.e. 71.74%, followed by 'Group B' Average percentage of relief i.e. 59.54%. In group B patients complain of reoccurrence of symptoms after stoppage of drug. It shows that effect of therapy/drug was more in Group A in comparison to Group B.



Overall Effect of Therapy in Group A.



Overall Effect of Therapy in Group B.



Total no of patients cure after treatment.

#### **CONCLUSION**

This clinical experiment was carried on 30 subjects with the objective of assessing the effect selected Ayurvedic drug/s or procedure on Asrigdara. Group A patients are administered with Bala Taila Nasya with Phaltrikadi Kwath while with Phaltrikadi Kwath in Group B. After the study, it can be concluded that both the groups showed a significant trend of reduction in the complaint but Group A showed better results with minimal reoccurrence due to the direct stimulation of hypothalamic-pituitary-ovarian axis by Nasya karma whereas, helped in reducing the fragility of endometrial capillaries and thus toning them which manifested to improvement in subjective parameters.

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