



Research Article

A CLINICAL STUDY TO EVALUATE THE EFFICACY OF *VASADI YOGA* IN THE MANAGEMENT OF *RAKTAPRADAR*

Nirma Narjary^{1*}, Dipak kumar Goswami²

¹PG.Scholar, ²Assistant Professor, Department of Prasuti Tantra and Stree Roga, Government Ayurvedic College and Hospital, Guwahati, Assam, India.

ABSTRACT

Raktapradar is a most common gynecological problem found in PTSR. It is not a disease but a symptom found in many gynaecological disorders. Most of the gynaecological disorder comes under the heading of *Yonivyapad* in Ayurvedic classics. It has an associated complication like *Pandu* and sterility. Hence *Vasadi churna* with *Tandulodak* is chosen to study its effect in *Raktapradar*. **Method:** A clinical trial was conducted in indoor and outdoor patient diagnosed with *Raktapradar*. The 30 patient was given with an Ayurvedic drug and monitored according to protocol including clinical and pathological parameter. The criteria for selection of patient are inclusive and exclusive. Patient from inclusive criteria have excessive bleeding p/v was selected. Clinical symptoms were assessed with four grades as follow no change, marked, moderate, and severe. Criteria for assessment were marked, moderate and mild. **Results:** Results were noted and it was observed that selected drug is safe and effective.

KEYWORDS: *Raktapradar*, *Vasadi yoga*, *Adhatoda vasica*, Bleeding per vagina.

INTRODUCTION

Ayurveda is a science of life which explain us how to live and enjoy a healthy life. From Vedic age people followed Ayurveda for curing their disease. Human life is constantly influenced by the rhythmic phenomenon operating in this universe. Health is the actual way of attaining longevity in all species including human being. The female menstrual cycle involves dramatic monthly hormonal changes affecting a women's emotional and physical state. *Acharya Charak* mentioned that *Garbha* (new progeny) can be resides only in *Suddha yoni*. That is why *Ayurveda* has explained woman's health in details and emphasized on all the preventive as well as curative measures to preserve it in the healthiest state. *Ayurveda* has described many fundamental concepts like *Dosha*, *Dhatu* with their *Updhatu* and *Mala*. *Artava* is the *Upadhatu* of *Rasa dhatu*. *Ati* means excessive and *Artava* means menstrual blood. In Ayurveda the condition of excessive bleeding during menstruation is known as *Raktapradar*. This condition arises when *Pitta* and *Vata* get vitiated.

Abnormal uterine bleeding is defined as any variation from the normal menstrual cycle, and includes changes in regularity and frequency of menses, in duration of flow, or in amount of blood loss^[1]. It is a problem mostly prevalent in reproductive age group worldwide and affects quality of life. It has got different detrimental effects on

individual and community. For instances, school and work absenteeism, interference with daily activities, limitation to socialization and higher intake of NSAIDs and haemostatics are positively associated with higher prevalence and intensity of menorrhagia.

Menorrhagia is essentially a symptom and not itself a disease. It affects 20-30% woman at sometime or other with significant adverse effect on the quality of life in terms of anaemia, cost of sanitary pads and interference in day-to-day activities. Several causes may prevail in a few cases, and attribute to excess bleeding. In excessive bleeding with regular cycle, H-P-O axis is intact, but endometrial changes get altered. It is observed that in these cases, PGI₂ (prostacyclin), which is a vasodilator is increased as compared to PGF_{2a} (carboprost) in endometrial tissue.

The treatment protocol for *Raktapradar* is based on correction of *Pitta dosa Anubandhi Vata dosha* along with *Rakta dhatu*. *Vata dosha* is the root cause of all the *Yoni dushti*^[2]. The drug selected for the present study is *Vasadi yoga* which corrects *Pitta-vaigunya* and thus pacifies *Apana vayu* in specific as *Apana vayu* is *Anubandha dosha* here and is responsible for *Raja Nishkramana*^[3].

Almost all *Ayurvedic* classics emphasized the concept of *Raktapradar* which highlights the

importance given to the subject. This study aimed at systematic compilation, analysis and interpretation of the concepts of *Raktapradar* with the contemporary science, understanding the concepts of abnormal uterine bleeding from an Ayurvedic perspective and to assess the efficacy of the trial drug i.e., *Vasadi yoga* in the treatment of it.

Various treatments like hormonal therapy, anti prostaglandin and anti fibrinolytic agents are available in modern health science. Many side effects have been observed because of medication and hysterectomy leading to hormonal imbalance and psychological upset in young fertile women. So keeping in mind I took *Ayurvedic* drug which are non-hormonal and safe that could provide effective alternative for *Raktapradar*. I have selected *Vasadi yoga* with *Tandulodak* which has been mentioned in *Yogaratanakar* due to its contents, cost effectiveness and disease healing property.

The combined formulation selected for treatment is based on following properties. *Vasa* have a property of *Rakta pittaghna* and its leaves act as vasoconstrictor. *Yasthimadhu* has property of *Dahashamak* and *Vatapittaghna* and *Misri* has *Vata*, *Pitta* and *Rakta Doshahara* properties along with *Tandulodak* as *Anupan* which increases the potency of the drug action so here I attempted to evaluate the efficacy of *Vasadi Yoga* with *Tandulodak* in the management of *Raktapradar*.

MATERIAL AND METHODS

METHOD

30 patient from experimental group as per previously stated criteria were selected and provided *Vasadi yoga* (5gm) twice daily orally with *Tandulodak* as *Anupan*.

Work Profile

Criteria for selection of patient were-

1. Inclusive Criteria

- Patient between age group of 12-50 year of age
- Patients with *Lakshana* of *Raktapradar* like prolong, excessive menstrual bleeding and intermenstrual bleeding. (According to *Ayurvedic* reference ^[4,5,6] (*C.S.Chi30/208*, *Su.S.Sa 2/18,19*, *A.S.Sa 1/11*)

2. Exclusive Criteria: Patient having other associated complications such as Fibroid, Polyp, Malignancy, Hypertension, Tuberculosis, Diabetes mellitus, Blood dyscracias was excluded from study point of view.

Investigation

Following investigations were done

a) Blood routine examination,

- b) Bleeding and Clotting Time, Blood sugar
- c) Platelet count
- d) VDRL, HIV, HBsAg, HCV
- e) USG lower abdomen to know about any pelvic pathology and endometrium
- f) Urine for HCG
- g) FSH, LH
- h) Others as required for the patient concerned.

Trial Methodology

The study was performed in a randomized open trial.

Preparation of the Trial Drug

Vasa plants are collected fresh from local area and cleaned in running water then dried properly in drier machine. Dried *Yasthimadhu* root and *Misri* was collected. After proper drying these entire ingredients were taken in equal quantity and was grinded and made into fine powder. Packaging done for prepared formulation where single packet of drug contains 150gm. The preparation is done in *Rasashala* of Govt. Ayurvedic College and Hospital. The *Churna* was tested in State Drug Testing Laboratory (AYUSH), Guwahati. Authenticity of material was confirmed by expert of respective field, there originality, purity was identified and selected as per standard mentioned in *Ayurvedic Pharmacopoeia of India (API)*.

Dose and Duration of Treatment

The prepared formulation is given in the dose 10gm in two divided doses after meal with 40ml *Tandulodak* (with each dose) for 3 consecutive menstrual cycle.

Assessment Parameter

Control trial selection of method patient from indoor and outdoor department as per previous stated criteria were selected. As per proforma of case sheet, detail history, clinical findings were recorded.

Following sign and symptoms for assessment were as follow

- **Raja Srava pramana:** It will be assessed by number of used sanitary pads per day (*Raja Pradirana*). Women were advised to use standard sized sanitary pads 15x7.5x2.5cm made of cotton and scoring is done purely on the basis of the patient's statement.
- **Raja Srava Kaal:** The duration of bleeding phase will be assessed by comparing with previous menstrual history the patient (*Raja srava avadhi*).
- **Anaritukaal:** Duration of intermenstrual period.
- **Vedana:** association of pain abdomen during menstruation

Gradation of the Sign and Symptoms**A) Srava kaala (Duration of Bleeding)**

Duration in Days	Remarks	Grading
2-3	Average	0
4-5	Mild prolonged	1
6-7	Moderately prolonged	2
8-10	Prolonged	3
>10	Very prolonged	4

B) Sravamaana (Quantity of bleeding)

No. of Pads used in 24 hours	Remarks	Grading
Maximum soakage of 1-2 pads in 24hours	Average	0
Maximum soakage of 3-4 pads in 24hours	Mild excessive	1
Maximum soakage of 5-6 pads in 24hours	Moderately excessive	2
Maximum soakage of 6-7 pads in 24hours	Excessive	3
Maximum soakage of more than 7 pads in 24hours	Highly excessive	4

C) Anaritukaal (Intermenstrual period)

Duration of intermenstrual period	Remark	Grading
26-30 days	Average	0
21-25 days	Short	1
15-20 days	Very short	2
<15 days	Extremely short	3

D) Vedana (pain during menstruation)

Extent of pain	Remark	Grading
No pain during menstruation	Average	0
Complaints of pain but do not require medical assistance, do not affect daily activity	Mild pain	1
Complaints of pain generally take random medicine, do not affect daily activity severely	Moderate pain	2
Complaints of pain, bound to take medicine and it is effective, affects daily activity	Severe pain	3
Complaints of pain, bound to take medicine and it is not that much effective, affects daily activity severely.	Very severe pain	4

RESULT

In this present study, total 30 numbers of patients were given treatment along with follow up of three consecutive cycles.

Pre-Observation**Duration of Menstrual Period**

It is evident from the study that maximum i.e., 50% patients were having duration of menstrual period of 8-10 days, while 46.67% had 6-7 days and 3.33% patients had menstrual period of duration 4-5 days. No patient was found with menstrual period more than 10 days.

Amount of Blood Loss per Cycle

It is evident from the study that maximum i.e. 43.33% patients were found with maximum soakage of 6-7 pads in 24 hours, while 40% patients were with maximum soakage of more than 7 pads in 24 hours, 10% patients were found with maximum soakage of 5-6 pads in 24 hours and 6.67% were found with maximum soakage of 3-4pads in 24 hours.

Duration of intermenstrual period

It is evident that maximum i.e., 66.67% patients were having duration of intermenstrual period of 26-30 days, while 26.67% had 21-25 days and remaining 6.66% patients had intermenstrual

period of duration 15-20 days. No patient was found with duration of intermenstrual period less than 15 days.

Association of pain with chief complaints

It is clear from the study that out of 30 patients, 8 patients i.e. 26.67% had no pain abdomen during menstruation. 14 numbers of patients i.e., 46.67% had complaints of pain during menstruation but do not require any medical assistance and it do

Demographic Review

not affect daily activity at all. 1 patient had complaints of pain generally take random medicine; do not affect daily activity severely. 4 numbers of patients i.e., 13.3% had complaints of pain which affect daily activities and bound to take medicine and it is effective. 3 numbers of patients i.e., 10% had complaints of pain which affect daily activities badly and bound to take medicine and it is not that much effective.

Table 2: Age Wise Distribution of 30 Patients

Serial no.	Age	Number of patients	Percentage
1	12-20 year	1	3.34%
2	21-30 year	7	23.34%
3	31-40 year	18	60%
4	41-50 year	4	13.34%

Table 3: Marital Status Wise Distribution of 30 Patients

Serial no.	Marital Status	Number of Patients	Percentage
1	Married	24	80%
2	Unmarried	6	20%

Table 4: Occupation Wise Distribution of 30 Patients

Serial no.	Occupation	Number of patients	Percentage
1	Student	3	10%
2	House -wife	20	66.67%
3	Service	7	23.34%

Statistical Review

Table 5: Effect of Trial Drug on Symptoms of Raktapradar on 1st Follow-up

S. No.	Symptoms	\bar{X}_{BT}	\bar{X}_{AT}	\bar{X}_{BT-AT}	SD_{BT-AT}	SE	t-value	P	Remarks
1	<i>Srava Kala</i> (N=30)	2.5	1.8	0.63	0.47	0.08	7.87	<.001	Highly Significant
2	<i>Sravapraman</i> (N=30)	3.1	2.5	0.6	0.55	0.1	6	<0.001	Highly Significant
3	<i>Anaritukaal</i> (N=10)	1.2	0.4	0.8	0.41	0.13	6.15	<0.001	Highly significant
4	<i>Vedana</i> (N= 22)	1.8	1.2	0.54	0.79	0.17	3.17	<0.01	Significant

Table 6: Effect of Trial Drug on Symptoms of Raktapradar on 2nd Follow-up

S. No.	Symptoms	\bar{X}_{BT}	\bar{X}_{AT}	\bar{X}_{BT-AT}	SD_{BT-AT}	SE	t-value	P	Remarks
1	<i>Srava Kala</i> (N=30)	2.5	1.2	1.26	0.50	0.09	14	<.001	Highly Significant
2	<i>Sravapraman</i> (N=30)	3.1	1.8	1.3	0.64	0.1	13	<.001	Highly Significant
3	<i>Anaritukaal</i> (N=10)	1.2	0.3	0.9	0.56	0.18	5	<.001	highly significant
4	<i>Vedana</i> (N= 22)	1.8	1	0.72	0.81	0.17	4.23	<.001	Highly Significant

Table 7: Effect of Trial Drug on Symptoms of Raktapradar on 3rd Followup

S.No.	Symptoms	\bar{X}_{BT}	\bar{X}_{AT}	\bar{X}_{BT-AT}	SD _{BT-AT}	SE	t-value	P	Remarks
1	Srava Kala N=30	2.5	0.9	1.6	0.55	0.10	16	<.001	Highly Significant
2	Sravapraman N=30	3.1	1.3	1.86	0.67	0.12	15.5	<.001	Highly Significant
3	Anaritukaal N=10	1.2	0.1	1.1	0.56	0.18	6.1	<.001	Highly significant
4	Vedana N= 22	1.8	0.6	1.2	0.96	0.2	6	<.001	Highly Significant

N= number of patients

Table 8: Final Assessment

Symptoms	Before treatment		After treatment							
			Cured		Moderate Improvement		Mild Improvement		Unchanged	
	No. of Patients	%	No. of Patients	%	No. of Patients	%	No. of Patient	%	No. of Patient	%
Srava Kala	30	100	03	10	27	90	00	00	00	00
Sravapraman	30	100	03	10	15	50	12	40	00	00
Anaritukaal	10	33.33	09	90	00	00	00	00	01	10
Vedana	22	73.33	10	45.45	6	27.27	01	4.54	05	22.7

After completion of the trial, the statistical evaluation showed following results in individual sign and symptoms:

- Srava Kala (Duration of Bleeding):** Clinically out of 30 total patients, all the 30 patients had the symptoms. After the treatment 3 patients i.e., 10% had complete cure, 27 patients i.e., 90% patients had moderate improvement.
- Srava Praman (Amount of Bleeding):** Clinically out of 30 total patients, all the 30 patients had the symptom. After the treatment 3 patients i.e., 10% had complete cure, 15 patients i.e., 50% patients had moderate improvement and 12 patients i.e., 40% shows mild improvement. No any patients remain unchanged.
- Anaritukaal (Duration of Intermenstrual Period):** Clinically out of 30 patients, 10 patients are found with shortened intermenstrual period. After treatment 9 patients i.e. 90% had complete cure and rest 1 patient had no improvement i.e. 10%.
- Vedana (pain abdomen during menstruation):** Clinically 22 patients out of 30 had the symptom. After treatment 10 patients i.e. 45.45% got complete cure, 6 patients i.e. 27.27% had moderate improvement, 1 patient i.e., 4.54% had mild improvement and 5 patients i.e., 22.7% had no improvement.

DISCUSSION

Probable Mode of Action of Trial Drug

In the present study the trial drug is formulated namely *Vasadi Yoga*. The trial drug *Vasadi*

Yoga has reference in "*Yogaratnakar strirogadhikar pradar chikitsa*".^[7]

The ingredients of *Vasadi Yoga* are- *Vasa*, *Yasthimadhu*, *Misri*. All the drugs were taken in equal parts and made into *Churna* form of 150gm each.

Except indications, there is no reference of *Rasa*, *Guna* etc of this formulation. Hence the *Rasa Guna* etc, whatever description of the individual drugs found is mentioned to have an overall idea in respective places. To understand this scientifically we should consider the related basic fundamentals, which are described in the classics as

- The conjugation of *Rasas (Rasa Sannipata)* to their mutual subordination and variation in processing on the basis of *Prakriti Sama Samavaya* and *Vikriti-Visham-Samavaya (Chakrapani)* theories are to be analyzed decide the total effect (*Samudaya Prabhava*) of the drug on the *Doshas* (or disease). It is because the active ingredients in a compound formulation show either antagonism (*Parasparena Cha Upahatanama*) or synergism (*Abhivardhana*) effects^[8]. (*Ch. Vi. 1/7*).
- The drugs are active due to their own inherent constituents (*Dravya Prabhava*), properties (*Guna Prabhava*) and both combined (*Dravyaguna Prabhava*) together in particular time, on reaching particular site, with a particular mechanism and objective.^[9] (*Ch Su. 26/13*)
- The different properties of a drug are inferred by observing their effects on the body^[10]. (*Su. Su. 46/521*)

Therefore keeping the above view in mind, we can establish the possible properties, action and mode of action of the trial drug by observing the clinical and pharmacological effect.

Hence the pharmacological property of *Vasadi Yoga* can be explained as

- *Rasa- Kashaya, Madhur*
- *Guna- ruksha, Laghu*
- *Virya- Sheeta*
- *Vipak- Katu*

Acharya Charak explained *Raktapradar* as disease of vitiated *Rakta* and *Pittavrit vata* and *Apana vayu*^[11]. (C.Chi 30/202)

Most of the ingredients of treatment of *Raktapradar* contain *Kashaya Madhur Rasa, Laghu Ruksha Guna, Sheeta Virya* properties due to *Kashaya Madhur Rasa*, it has *Grahi* action so it is indicated in all bleeding condition.

In the pathogenesis of *Raktapradar Chala Guna* of *Vata Dosha* and *Drava Guna* of *Pitta Dosha* increase the amount of blood. Hence these drugs might affect the *Sara* and *Drava Guna* of *Pitta Dosha* with the help of *Ruksha, Laghu Guna* and *Kashaya Rasa* so this could be reason in reducing the amount of bleeding.

Cholesterol the precursor of all steroid hormones, especially in female is responsible for more production of oestrogen. *Kaphashamak* and *Lekhaniya karma* are probably carried out by *Laghu and Ruksha Guna* of *Vasa* therefore it decreases the production of oestrogen leading to reduced hyperplasia of endometrium.

Hence in the pathogenesis of *Raktapradar, Chala Guna* of *Vata, Sara* and *Drava Guna* of *Pitta* increase the amount of blood, hence these drug might affect *Sara* and *Drava Guna* of *Pitta Dosha* with the help of *Ruksha Laghu Guna* and *Kashaya Rasa* as a result it decrease the amount of bleeding.

Discussion on the Observation of Demographic Profile

From age point of view, it was found that out of 30 patients, maximum number of patients i.e. 60% belonged to the age group 31-40 years, followed by 23.34% of age group 21-30 years and 3.34% belong to age group of 12-20 years each. It may indicate towards the less awareness about self health and stressful life of housewives with age above 31years.

Data shows married woman suffers from menorrhagia more i.e., 80% compared to unmarried woman i.e., 20%. That may indicate towards stressed psychological status and less health awareness among housewives as this study also shows maximum number of patients i.e., 66.67% were

housewives followed by 23.34% were service woman and only 10% patients were students.

DISCUSSION ON RESULT

On Cardinal Symptom of the disease: After three months of the trial, the findings are as shown below

1. On *Sravakala* (duration of bleeding) after treatment $t_{29}=16$, $P<.001$, hence the effect of trial drug is found highly significant.
2. On *Sravapraman* (quantity of bleeding) after treatment $t_{29}=15.5$, $P<.001$, hence the effect of trial drug is found highly significant.
3. On *Anaritukaal* (Intermenstrual duration) after treatment $t_9=6.1$, $P<.001$, hence the effect of trial drug is found highly significant.
4. On *Vedana* (pain abdomen during menstruation) after treatment $t_{21}= 6$, $P<.001$ hence the effect of trial drug is found highly significant.

Table 6 and table 7 showed that the trial drug showed its effect from the first follow-up.

CONCLUSION

1. The clinical condition of *Raktapradar* is more or less similar to abnormal uterine bleeding or Dysfunctional uterine bleeding.
2. Treatment protocol of *Raktapradar* should be done in the line of *Raktapitta Chikitsa*.
3. The formulation selected for the present study is *Vasadi yoga* where *Vasa* is considered as best *Raktapittaghna* drug. Besides *Tandulodak* can be prescribed as best *Anupan in Raktapradar*. Other ingredients such as *Yasthimadhu* and *Misri* act as *Pittashamak*.
4. The trial drug showed encouraging result in symptoms associated with *Raktapradar* without having any toxicity or adverse effect in the body.
5. Trial drug has shown to be effective in excessive and prolong bleeding by reducing both amount and duration of blood loss, normalizing intermenstrual period and also relieved pain.
6. Drug is very cheap, widely available and can be easily prepared at home.
7. Further study on larger sample with assessment of biochemical and experimental parameter are needed for more precise conclusion of the drug in order to establish its efficacy in *Raktapradar*.

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***Address for correspondence**

Dr Nirma Narjary

PG Scholar,

Department of Prasuti Tantra and Stree Roga, Government Ayurvedic College and Hospital, Guwahati, Assam, India.

Email: nirmanarzary@gmail.com

Contact no: 8876996358

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