



## A CLINICAL STUDY TO ASSESS THE EFFICACY OF 'PRADARARIPU RASA' IN ASRIGDARA W.S.R TO DUB

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### ABSTRACT

*Asrigdara* is a condition that physicians have to face in day to day practice. It's a common medical disease seen in women, which can cause significant disturbances physically as well as mentally. In modern science its sign & symptoms can be easily correlate with dysfunctional uterine bleeding. Deviation in the menstrual cycle which may be excessive or low is filled with fear of some serious pathology of internal genital organs. *Asrigdara* characterized by excessive, prolonged, and menstrual or inter menstrual bleeding. This condition is distressing and potentially disabling. In classics many causative factors like *Ati lavana amala katu rasa sevana*, *viruddaahara* and *vihara's* like *chinta bhaya krodha* are explained as causative factors of

*Asrigdara*. Normalising the amount of flow and curing the associated symptoms are fundamental principles of treatment to be adopted.

**KEY WORDS:** *Asrigdara*, Dysfunctional uterine bleeding, Distressing and potentially disabling.

### INTRODUCTION

DUB 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>

30% of the women population is suffering from Dysfunctional Uterine Bleeding (DUB) among which 10% women are in their reproductive age. Annually 75,000 hysterectomies are being conducted, in that 30% are due to DUB.

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 *Pradararipu rasa* in the management of *Asrigdara*.

Thus the present study is being undertaken to scientifically study and validate the effect of *Pradararipu rasa*<sup>[3]</sup> explained under the context of *pradara* for the management of *Asrigdara*.

## OBJECTIVES OF THE STUDY

1. To assess the efficacy of *Pradararipu rasa* in *Asrigdara*
2. A conceptual study of *Asrigdara*

## METHODOLOGY

### 1. STUDY DESIGN

The study was randomized double arm controlled open label study; phase III clinical study.

### 2. SAMPLING TECHNIQUE

The subjects who fulfilled the inclusion and exclusion criteria and complying with the informed consent (IC) were selected using lottery method of random sampling technique.

### 3. SAMPLE SIZE

A comparative clinical study where in 40 Patients diagnosed as *Asrigdara* were randomly assigned into two groups i.e., Group A, Group B each comprising of 20 patients.

**DIAGNOSTIC CRITERIA**

1. *Lakshanas* of *Asrigdara*.
2. Signs and Symptoms of DUB.

**INCLUSION & EXCLUSION CRITERIA****INCLUSION CRITERIA**

1. Patients of either gender in between 18-50 years of age.
2. Patients presenting with *Lakshanas* of *Asrigdara*.
3. Patients presenting with signs and symptom of DUB. Excessive bleeding at least for 2 cycles.

**EXCLUSION CRITERIA**

1. Patients with Uterine Pathology.
2. Incomplete Abortion.
3. Thyroid dysfunction.
4. Bleeding other than of uterine origin.
5. Hematological & Coagulatory disorders.

**INTERVENTION**

40 patients of *Asrigdara* were randomly selected and divided into 2 groups, Group A and Group B.

**Group A:**

Patients of Group A will be placed on *pathya* for 45 days.

**Group B:**

Patients of Group B will be placed on *pathya*+ *Pradararipu rasa* capsule 250 mg thrice a day, for 45 days.

**PRADARARIPU RASA**

Ser.no	INGREDIENTS	QUANTITY
1	<i>Shoditha Parada</i>	168.78 grms
2	<i>Shodihta Gandaka</i>	168.78 grms
3	<i>Naga Bhasma</i>	168.78 grms
4	<i>Dharu Haridra Rasanjana</i>	506.25grms
5	<i>Lodra kashaya</i>	Quantity sufficient
6	<i>Vasa puta pakwa kashaya</i>	Quantity sufficient

### Assessment Criteria

1. The clinical findings were noted in specially prepared case proforma before treatment

**Before treatment:** First day of treatment.

2. **During treatment follow up:-** menses during treatment

3. **After treatment, 1<sup>st</sup> follow up:-** 1<sup>st</sup> menses after treatment

4. **After treatment, 2<sup>nd</sup> follow up:-** 2<sup>nd</sup> menses after treatment.

5. **After treatment, 3<sup>rd</sup> follow up:-** 3<sup>rd</sup> menses after treatment.

6. The parameters considered for the study were graded and scoring pattern from 0-3 was adopted for the purpose of statistical analysis.

### Parameters

1. Amount of bleeding / *Artava Pramana* (Assessment by Pads)

2. Duration of bleeding /*Artavasrava Avadhi*

3. Inter-menstrual period

4. Consistency

5. Intensity of lower abdominal pain

6. Body ache

7. Low Back ache

8. Giddiness

9. Weakness

10. Pallor

11. Thirst

12. Drowsiness

### GRADATION INDEX

Ser.no	GRADES	0	1	2	3
1	<i>Artava Pramana</i>	2-3 pads/ day	4-5 pads	6-7 pads	More than 8 pads
2	<i>Artavasrava Avadhi</i>	2-5 days	6-10 days	11-15 days	More than 16 days
3	Inter-menstrual period	28-35 days	Once in 20 days	Once in 10-15 days	Continues flow
4	Consistency	Thin	Mucoid	Mucoid with clots	Clots (Lorge size)
5	Intensity of lower abdominal pain	No Pain	Mild pain	Moderate pain	Sever pain
6	Body ache	No Pain	Pain without disturbing routine activity	Pain disturbing daily activity	Not able to perform daily activity due to pain

7	Low Back ache	No pain	Pain present but able to sit and sleep	Due to pain not able to sit but can sit	Not able to sleep also
8	Giddiness	Present			absent
9	Weakness	No Weakness	Feeling Weakness after doing some work	Feeling weakness in between some work	Feeling weakness without any work
10	Pallor	No Pallor	Pallor in conjunctiva	Pallor in conjunctiva and skin	Pallor in conjunctiva skin and palmar creases
11	Thirst	No <i>trishna</i>	<i>Ishat trishna</i>	<i>Muhurmuhu Trishna</i>	<i>Satata Trishna</i>
12	Drowsiness	No Drowsiness	Occasional drowsy	Drowsy while sitting for a long time	Drowsy while sitting for a short span of time

### Statistical analysis

For the statistical analysis the data obtained in both the groups were recorded, presented in tabulations.

For the Statistical Analysis, Paired t-test was applied within the group and unpaired t-test was applied between the groups for parameters amount of bleeding, duration of bleeding, inter-menstrual bleeding, and consistency of bleeding.

To assess, the intensity of lower abdominal pain, body ache, back ache, giddiness weakness, pallor, thirst, drowsiness. Chi-square test was applied within the group and between the groups.

### OBSERVATION

PARAMETER	CATEGORY	VALUE	%
Age	30-34 yrs	10	25%
Sex	Female	40	100%
Religion	Hindu	21	52.1%
Marital status	Married	37	92.5%
Occupation	Homemaker	35	87.5%
Education	Primary	16	40%
Socio economic status	Middle class	24	60%
Habitat	Urban	39	97.5%
Diet	Mixed	30	75%
<i>Rasa pradanata</i>	<i>Amla</i>	15	37.5%
Bowel	Normal	24	60%
Sleep	Sound sleep	31	77.5%
<i>Prakruthi</i>	<i>Pitta kapha</i>	18	45%
Built	Moderate	28	70%

Satva	Madyama	25	62.5%
Abhyavara shakti	Madhyama	25	62.5%
Jarana shakti	Madhyama	26	65%
Vyayama shakti	Avara	34	85%
Contraceptive	tubectomy	19	47.5%

## RESULTS

RESULTS OF PATHYA ON ASSESSMENT PARAMETERS WITHIN GROUP A						
Symptoms	Mean diff	SD	PSE	t' value	p value	Remarks
Amount of bleeding	1.35	0.81272	0.181	7.424	<0.001	HS
Duration of bleeding	1.4	0.82072	0.183	7.624	<0.001	HS
Inter menstrual bleeding	1.5	0.606977	0.135	11.046	<0.001	HS
Consistency	1.15	0.587143	0.131	8.755	<0.001	HS

Symptoms	x <sup>2</sup> value	p value	Remarks
Lower abdominal pain	18.66	<0.001	HS
Body ache	14.096	<0.01	HS
Low back ache	18.272	<0.001	HS
Weakness	17.6	<0.001	HS
Pallor	17.366	<0.001	HS
Thirst	11.98	<0.01	HS
Drowsiness	15.76	<0.01	HS
Giddiness	19.7	<0.001	HS

RESULTS OF PATHYA + PRADARARIPU RASA ON ASSESSMENT PARAMETERS WITHIN GROUP B						
Symptoms	Mean diff	SD	PSE	t' value	p value	Remarks
Amount of bleeding	1.85	0.74516	0.166	11.097	<0.001	HS
Duration of bleeding	2.3	0.571241	0.127	17.99	<0.001	HS
Inter menstrual bleeding	2.15	0.587143	0.131	16.368	<0.001	HS
Consistency	1.65	0.812728	0.181	9.074	<0.001	HS

Symptoms	x <sup>2</sup> value	p value	Remarks
Lower abdominal pain	26.8	<0.001	HS
Body ache	36.8	<0.001	HS
Low back ache	32.7760	<0.001	HS
Weakness	29.56	<0.001	HS
Pallor	29.56	<0.001	HS
Thirst	32.72	<0.001	HS
Drowsiness	26.66	<0.001	HS
Giddiness	29.56	<0.001	HS

RESULTS ON ASSESSMENT PARAMETERS BETWEEN GROUP A & GROUP B									
Symptoms	BT/ AT	GROUP	MEAN	SD	SE	PSE	t' value	p value	Remarks
Amount of bleeding	BT	A	0.55	0.686	0.153	0.2045	0.488	>0.05	NS
		B	0.45	0.604	0.135				
	AT	A	1.45	0.825	0.184	0.233	1.285	>0.05	NS
		B	1.75	0.638	0.142				
Duration of bleeding	BT	A	0.55	0.604	0.135	0.201	1.485	>0.05	NS
		B	0.85	0.670	0.150				
	AT	A	1.45	0.825	0.184	0.224	3.786	<0.01	HS
		B	2.3	0.571	0.127				
Inter menstrual bleeding	BT	A	0.85	0.670	0.150	0.199	1.00	>0.05	NS
		B	0.65	0.587	0.131				
	AT	A	1.6	0.502	0.112	0.196	2.55	<0.05	S
		B	2.1	0.718	0.160				
Consistency	BT	A	0.6	0.820	0.183	0.215	0.929	>0.05	NS
		B	0.4	0.502	0.112				
	AT	A	1.35	0.745	0.166	0.246	1.216	>0.05	NS
		B	1.65	0.812	0.181				

RESULTS ON ASSESSMENT PARAMETERS BETWEEN GROUP A & GROUP B				
Parameter	DT/AT	$\chi^2$ value	p value	Remarks
Lower abdominal pain	DT	0.2018	>0.05 <b>0.05</b>	NS
	AT	3.272	>0.05	NS
Body ache	DT	6.46	>0.05	NS
	AT	5.62	<0.05	NS
Low back ache	DT	0.488	>0.05	NS
	AT	2.472	>0.05	NS
Weakness	DT	0.00	>0.05	NS
	AT	7.058	>0.05	NS
Pallor thirst	DT	0.00	>0.05	NS
	AT	3.242	>0.05	NS
Drowsiness	DT	0.98	>0.05	NS
	AT	4.444	>0.05	NS
Pallor thirst	DT	3.968	>0.05	NS
	AT	4.44	>0.05	NS
Drowsiness	DT	0.88	>0.05	NS
	AT	2.104	>0.05	NS

#### DISCUSSION ON DRUG-PRADARIPU RASA

- *Vasa*<sup>[4]</sup> which is a *rakta stambhaka*, and *vata, pitta kapha nashaka*. It is also a *trishna shamaka*. The drug has chemicals which act as spasmolytic and potent contractile of uterus. *Vasa* is *trishna shamaka*.
- *Lodhra*<sup>[5]</sup> which is also *rakta stambhaka, vata-pitta nashaka* in nature. The drug has chemicals which are act as peripheral vaso constrictor.

- **Rasanjana** is made out of *Daruharidra*<sup>[6]</sup>, which is *rakta stambhaka*. *vata –pitta nashaka* in nature. The drug has chemicals which are act as peripheral vaso constrictor. **Rasanjana** has *ushna singdha guna* acting as *vata shamaka* and *rasayana* in nature. It is also *agni vardhaka*.
- **Naga bhasama** *ati ushna* in nature having *snigda guna* and also having *sroto shodhaka* property by its *kshara guna*. It is *agnivardaka*.
- **Lodhra** and **vasa** are *katu vipaka dravya*. *Katu rasa* having *agni deepana* property help to normalize the *jataragni* and *dhatwagni*. *Lodra, vasa* are *sheeta veerya* by and act as *pitta shamaka*.
- **Kajjali** is the homogeneous mixture of *shudda Parada* and *shudda gandaka*. When *kajjali* is mixed with any drug, it enhances the potency of that drug.
- **Madhu** is *vata shamaka* by its *Madura rasa Madura vipaka* and *ushnaveerya*. The *kashaya anurasa* also act as the *stambhaka, grahi* and do the *drava shoshana*. *Madhu* is a good catalyst. By its *Madura rasa* and *Madura vipaka* it acts on the *pitta*. *Madhu* is *agni deepaka*.

## CONCLUSION

- In both the groups, within the group analysis shows that the effect of treatment was statistically highly significant during the treatment and after the treatment on all the parameters.
- Though both the groups showed significant changes after treatment, within the group analysis however on comparing *t – values* and *chi square values*, it can be inferred that Group B has showed better result when compared to Group A.

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