



## A CLINICAL STUDY TO EVALUATE THE EFFICACY OF KUTAJASTAKA IN THE MANAGEMENT OF ASRIGDARA(DYSFUNCTIONAL UTERINE BLEEDING)

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### ABSTRACT

**Objectives :** *Asrigdara* characterized by excessive, prolonged, menstrual or inter menstrual bleeding. In the present era it is the commonest among all gynecological problems. Any abnormality in *Rituchakra* (menstrual cycle) leads excessive and irregular uterine bleeding which is known as "*Asrigdara*" in classical text. it affects the physical and psychological health of a woman which can even hamper her day to day life as well as a great curse for working women. In modern science its sign & symptoms can be correlated with dysfunctional uterine bleeding. The treatment modalities in modern offer hormonal treatment or surgeries which is never without its undesirable side effects. Keeping this in view, it was decided to conduct a study on most prevalent disorder in present times called *Asrigdara*. The treatment aims is to providing an effective method of treatment without any side effects and reducing the surgical interventions. According to *Ayurveda* *Asrigdara* is basically related to *Pitta* and *Rakta Dushti* with *Apan Vayu Vaigunya*. **Methodes :** In this clinical study 30 patients of *asrigdara* were given *Kutajastka* in *churna* form. **Observation:** Very significant improvement was observed in symptoms of *Asrigdara* like Amount & duration of bleeding. Moreover there no side effects were observed. **Conclusion :** The drug has the properties of *Pitta Shamaka* , *Raktastambhak*, *Raktapittahara* and, *Deepana-Pachana*. due to that it is effective in *Asrigdara*

**KEYWORDS :** *Asrigdara*, *Raktadusti*, *Deepana-pachana* *Kutajastaka*

### INTRODUCTION

A Woman's health is the point of concern for her family, society and culture because any physical or mental disturbance can disturb her normal menstrual cycle. Any abnormality in *Rituchakra* (menstrual cycle) leads excessive and irregular uterine bleeding, which is known as "*Asrigdara*" in classical text. *Acharya Charaka*<sup>1</sup> has mentioned *Asrigdara* in *chikitsa sthana- 30*<sup>1</sup> chapter that the condition where there is excessive flow of *raja* (menstrual blood) is known as *Asrigdara*. *Acharya Susruta*<sup>2</sup> mentioned this in *sharir sthana-2*<sup>2</sup> chapter that due to excessive coital act, there will flow of *artava* during any time of *rituchakra* is known as *Asrigdara*.

According to *Astanga Samgraha*<sup>3</sup>, the *Asrik* which flows monthly in a woman when increased in amount or duration is known as *Asrigdar* or *pradar* or *raktayoni*. *Acharya Madhav*<sup>4</sup> mentioned that the condition where there is excessive and painful bleeding per vagina is known as *Asrigdara*. Besides *Asrigdara*, some other conditions (in *yoni vyapad* and *artav vyapad*) are also mentioned similar to *Asrigdara*. These are *Raktaja* and *pittaja artavadusti*, *Lohitaksara yoni vyapad*, *Raktayoni* and *Asrija yoni vyapad*

In the present study, Dysfunctional Uterine Bleeding is considered as a classical feature and a part of disease *Asrigdara*. Dysfunctional Uterine Bleeding (DUB), According to European Society of Human Reproduction and Embryology is "*Excessive bleeding (excessively, heavy, prolonged, or frequent) of uterine origin, which is not due to demonstrable pelvic disease, complications of pregnancy or systemic disease*". The current modalities of treatment for the management of Dysfunctional Uterine Bleeding are only symptomatic and does not ensure permanent cure for the disease. Researches are going on to understand the pathology of Dysfunctional Uterine Bleeding, which suggests that the disturbed haemostatic mechanism, altered angiogenesis and disturbed inflammatory responses are causes of Dysfunctional Uterine Bleeding but Modern science is unable to tackle with these endometrial responses. Conventional hormonal treatment has its limitations and associated with their side effects and nothing to do with correction of basic pathology. After a thorough review of *Ayurvedic* literature the drug *Kutajastaka*<sup>5</sup> has been selected

on the basis of reference available in *Baishajya ratnavali* , *Atisaradhikar* because all the 8 drugs have certain common properties i.e. *Pittakapha Shamaka* and, *Rakta shodhaka* and *Stambhaka*, *Raktapittahara* properties. These properties are helpful in *samprapti vighatana*, effective control and cure of disease *Asrigdara* the drugs has mentioned in *atisaradhikar* it is also indicated in the diseases of *raktaarsha*, *raktapitta*, and *Asadhya asrigdara*.

### AIMS AND OBJECTIVES OF THE STUDY

The present research study has been undertaken with the following objectives

- To review ayurvedic and related modern literature regarding *Asrigdara*
- To study the drug *Kutajastaka* in terms of their *rasa*, *guna*, *viry*, *vipak*, etc
- To evaluate the efficacy of *Kutajastaka* in the management of *Asrigdara*

### MATERIAL&METHODS

#### SOURCE OF DATA

- 30 numbers of patients of *Asrigdara* are selected from Out patient department and In patient department of Govt. Ayurvedic College Hospital, Dept. of Prasuti Tantra evum Stree Roga.

### COUNSELING AND CONSENT

- All the patients in the study were done proper counseling and written consent were taken from each and every patient before initiation of the study

### ETHICAL CLEARANCE

The study was started after getting approval by the institutional ethical committee (Ref No. IEC/19/20-209)

### SELECTION CRITERIA

Based on inclusion and exclusion criteria-

#### 1. INCLUSION CRITERIA

- Age group from menarche to menopause.
- Having moderate to heavy bleeding considering duration and quantity of bleeding during *Artava Kala* (whole menstrual cycle)

**2. EXCLUSION CRITERIA**

- Cases of menorrhagia associated with pelvic pathologies like uterine fibroid, polyp, malignancy of reproductive organs etc.
- Pregnant lady
- Having positive report for VDRL, HIV, HCV, HBsAg
- Organic involvement with malignancy
- Bleeding disorder
- Patient with uterine & pelvic pathology
- Acute episodes of DUB
- Hb% < 8gm/dl

**INVESTIGATIONS**

1. Blood Routine Examination, ABORH
2. Bleeding and Clotting Time, Random blood sugar
3. Platelet Count
4. VDRL, HIV, HBsAg, Anti Hcv
5. T3, T4, TSH
6. USG: USG lower abdomen (to know pelvic pathology)
7. Urine routine examination and culture/sensitivity
8. Urine for hCG

**TRIAL METHODOLOGY**

The study was performed in a randomized open trial

**PREPARATION OF THE TRIAL DRUG**

The *Kutajastaka*<sup>10</sup> contains 8 ingredients which are

1. KUTAJA (*Holarrhena antidysenterica* Linn),
2. SHALMALI (*Salmaliamalala barica* Schott & Endl)
3. PATHA (*Cissampelos pareira* Linn)
4. SAMANGA (*Mimosa pudica* Linn)
5. MUSTAK (*Cyperus rotundus* Linn)
6. BILVA (*Aegle marmelos* Corr)
7. ATIVISHA (*Aconitum heterophyllum* Wall. Ca)
8. DHATKI (*Woodfordia fruticosa* Kurz)

**PREPARATION**

All the ingredients used part are collected fresh from local area and cleaned in running water then dried properly. After proper drying all are grinded and made into fine powder with equal amount. Single packageing done which contain 180 gm. The preparation is done in *Rasashala* of Govt. Ayurvedic College and Hospital, Jalukbari, Guwahati and The *churna* was tested in State Drug Testing Laboratory (AYUSH), Guwahati.

**DOSE:** ½ *karsha* (approx 6 gm) in 2 divided doses before food

**Anupana:** Luke warm water

**Duration of treatment:** 3 consecutive menstrual cycle

**Follow up:** After each menstrual cycles upto 3<sup>rd</sup> month

**PARAMETER FOR ASSESSMENT**

The cardinal symptoms are

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

**Associated symptoms-**

- *Kati-sroni-vanksan ruja* (pain in low-back, pelvic area and upper thigh)
- *Hrit parsha-pristha vedana* (abdominal cramps and back pain)
- *Daha* (burning sensation during bleeding)

- *Jwara* And *Bhrama* (fever and dizziness)
- *Arochak* (loss of appetite)
- *Chardi* (nausea)

**GRADATION OF THE 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) Srava pramaana (Quantity of bleeding)**

Nos. 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) Anaritu kaal (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	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, affect daily activity	Severe pain	3

**E) Associated symptoms**

Serial no.	Associated Symptom	Present	Impr oved	Cured/ Absent
1	<i>Kati-shroni-vanksanaruja</i> (low back & groin pain)	2	1	0
2	<i>Hrit-parsha-pristharuja</i> (upper back pain)	2	1	0
3	<i>Daha</i> (burning sensation)	2	1	0
4	<i>Jwara</i> and <i>bhrama</i> (fever & dizziness)	2	1	0
5	<i>Arochaka</i> ( loss of appetite )	2	1	0
6	<i>Chardi</i> (nausea)	2	1	0

**STATISTICAL ASSESSMENT OF RESULT:** The mean ± S.D before treatment of each sign & symptoms was compared with that of the after treatment. The pair t- test was used for test of significances & different sign & symptoms were assessed through p-value.

**Table 1: Effect of trial drug on cardinal symptoms of *Asrigdara* on 1<sup>st</sup> followup**

Sl. No.	Symptoms	$\bar{X}_{BT}$	$\bar{X}_{AT}$	$\bar{X}_{BT-AT}$	SD <sub>BT-AT</sub>	t-value	P	Remarks
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1	Srava Kala(durati on of menstrual cyces) N=30	2.57 ±.50	1.83 ±.46	0.74	0.04	8.93	<.001	Highly Significant
2	Srava praman (amout of bleeding) N=30	2.97 ±.76	2.5 ±.73	0.47	0.03	5.04	<.001	Highly Significant
3	Anaritu kaal (intermenstrual period) N=10	0.4 ±.6	0.13 ±.35	0.27	0.27	3.25	<.001	significan
4	Vedana ( pain during menstrato n) N=22	1.33 ±.1	0.93 ±.78	0.4	0.52	3.03	<.001	Significa

N= number of patients ,BT: Before Treatment, AT: After Treatment- t-test of significance, p- probability. < ---- less than , > ----greater than,

Interpretation of 'p' value-

- Insignificant or Not significant (NS or NQS) - p>0.05
- Significant (S) -p<0.05
- Significant -p<0.01
- Highly Significant -p<0.001

This study shows that highly significant relief was observed on duration, amount of bleeding (*srava kala* and *srava praman*) while significant results were observed in intermenstrual period and pain during menstruation(*anaritu kaal* and *vedana*)

**Table 2: Effect of trial drug on cardinal symptoms of Asrigdara on 2<sup>nd</sup> followup**

Sl. No.	Symptoms	$\bar{X}_{BT}$	$\bar{X}_{AT}$	$\bar{X}_{BT-AT}$	SD <sub>BT-AT</sub>	t- value	P	Remarks
1	Srava Kala(duration of menstrual cyces) N=30	2.57 ±.50	1.23 ±.43	1.23	0.07	15.23	<.001	Highly Significant
2	Sravapraman(a mout of bleeding) N=30	2.97 ±.76	1.77 ±.68	1.2	0.08	9.20	<.001	Highly Significant
3	Anaritukaal (intermenstrual period) N=10	0.4 ±.6	0.1 ±.3	0.3	0.31	3.07	<.001	significa
4	Vedana( pain during menstraton) N=22	1.33 ±.1	0.7 ±.7	0.63	0.59	4.08	<.001	Significa

N= number of patients ,BT: Before Treatment, AT: After Treatment

Interpretation of 'p' value-

- Insignificant or Not significant (NS or NQS) - p>0.05
- Significant (S) -p<0.05
- Significant -p<0.01
- Highly Significant -p<0.001

This study shows that highly significant relief was observed on

, duration, amount of bleeding (*srava kala* and *srava praman*) while significant results were observed in intermenstrual period and pain during menstruation(*anaritu kaal* and *vedana*)

**Table 3: Effect of trial drug on cardinal symptoms of Asrigdara on 3<sup>rd</sup>/ final followup**

Sl. No.	Symptoms	$\bar{X}_{BT}$	$\bar{X}_{AT}$	$\bar{X}_{BT-AT}$	SD <sub>BT-AT</sub>	t- value	P	Remarks
1	Srava Kala(duratio n of menstrual cyces) N=30	2.57 ±.50	0.9 ±.31	1.67	0.19	16.70	<.001	Highly Significant
2	Sravaprama n(amout of bleeding) N=30	2.97 ±.76	1.27 ±.64	1.7	0.12	15.62	<.001	Highly Significant
3	Anaritukaal (intermenstrual period) N=10	0.4 ±.6	0.03 ±.18	0.37	0.44	3.27	<.001	significa
4	Vedana ( pain during menstraton ) N=22	1.33 ±.1	0.33 ±.48	1	0.82	5.21	<.001	Significa

N= number of patients ,BT: Before Treatment, AT: After Treatment

Interpretation of 'p' value-

- Insignificant or Not significant (NS or NQS) - p>0.05
- Significant (S) -p<0.05
- Significant -p<0.01
- Highly Significant -p<0.001

This study shows that highly significant relief was observed on , duration, amount of bleeding (*sravakala* and *srava praman*) while significant results were observed in intermenstrual period and pain during menstruation(*anaritu kaal* and *vedana*)

**Table 4:Effect of trial drug on associated symptoms of Asrigdara on 3<sup>rd</sup> followup**

Sl. No.	Symptoms	$\bar{X}_{BT}$	$\bar{X}_{AT}$	$\bar{X}_{BT-AT}$	SD <sub>BT-AT</sub>	t value	P	Remarks
1	Kati-shroni-vanksanru ja N=21	1.27 ±1.0	0.47 ±.48	0.8	0.53	5.44	<0.01	Significa
2	Hrit-parsa-pristharuja N=12	0.8 ±1.0	0.37 ±.49	0.43	0.52	4.18	<0.01	Significa
3	Daha N=10	0.53 ±.90	0.1 ±.31	0.43	0.59	3.07	<0.01	Significa
4	Jwara and bhrama N=0	0	0	0	0	0	0	0
5	Arochak N=-0	0	0	0	0	0	0	0
6	Chardi N=0	0	0	0	0	0	0	0

N= number of patients ,BT: Before Treatment, AT: After Treatment

Interpretation of 'p' value-

- Insignificant or Not significant (NS or NQS) - p>0.05

- Significant (S) -  $p < 0.05$
- Significant -  $p < 0.01$
- Highly Significant -  $p < 0.001$

This study shows that highly significant relief was observed on , duration, amount of bleeding (*sravakala* and *srava praman*) while significant results were observed in inter menstrual period and pain during menstruation (*anaritu kaal* and *vedana*)

## DISCUSSION

Discussion holds the most important part in any kind of research as it gives a scope to analyse the subject matter with logic and reasoning. In other words we can say that discussion is the extract of matter described in any research.

## PROBABLE MODE OF ACTION OF TRIAL DRUG

*KUTAJASTAKA* contains 8 drugs.

### A. BASED ON RASA:

- Among eight drugs, six drugs are having *tikta*, *kashaya rasa* and two are having *katu rasa*.
- Tikta & Katu rasa*: *Dipana & pachana* → *Agni vardana & amapachana* → *srotosodhana* → *Prakrita rasa* and *rakta dhatu* formation.
- Kashaya rasa*: *Stambhana*, *Grahi*, *Sleshmahara*, *Raktapittahara* → Thus help to reduce the duration and amount of bleeding.

### B. BASED ON GUNA:

- Majority of the drugs possesses *laghu* and *rukshaguna*.
- Laghu*: Have *srotosodhana* property does *raktasodhana*
- Rukshaguna*: It possess *Sthambhana & Shoshana* properties. *Sthambhana* directly and *shoshana* indirectly reduce the duration and amount of bleeding by absorption of *drava pitta*.

### C. BASED ON VIRYA:

- Majority of drugs possesses *sheeta veerya*.
- Sheeta virya* have *raktapitta hara* and *stambhaka*, properties which helps in relieving the symptoms of *asrigdara*.

### D. BASED ON VIPAKA:

- Katu vipaka* helps in relieving the symptoms of *asrigdara* by its *laghu* and *kaphapitta shamaka guna*.

### E. BASED ON KARMA:

- Majority of drugs possess *Raktapittahara*, *Raktasodhana*, *Raktastambhaka*, *Dhatushoshana*, *Sothahara*, and *Vranaropana* properties. All these properties of drugs act according to the *vyadhi pratyaneeka chikitsa*.

## DISCUSSION ON CLINICAL FINDINGS

- In the present study 30 patients are randomly selected for the trial.
- Each patient was examined clinically on the basis of prepared research proforma.

## DISCUSSION ON RESULT

### The Main Cardinal Features -

#### 1. *Srava Kala* (duration of bleeding):

- Out of 30 patients, all the 30 patients had the symptom. After treatment 18 patients i.e 60% had complete cure, 10 patients i.e 33.3% patients had moderate improvement, and 2 patients i.e 6.66% had mild improvement

#### 2. *Srava praman* (amount of bleeding):

- Out of 30 patients, all the 30 patients had the symptom. After the treatment 20 patients i.e. 66.6% had complete cure, 7 patients i.e.23.3% patients had moderate improvement and 3 patients i.e. 10% shows mild improvement. No any patients remain unchanged.

#### 3. *Anaritu kaal* (duration of intermenstrual period):

- Out of 30 patients, 10 patients are found with shortened intermenstrual period. After treatment 4 patients i.e. 40% had complete cure and 2 patients had mild improvement i.e. 20%. And 1 patients i.e 10% had no improvement

#### 4. *Vedana* (pain abdomen during menstruation):

- Out of 30 patients 22 patients had the symptom. After treatment 13 patients i.e. 59.09% got complete cure, 9 patients i.e. 40.9% had moderate improvement, no patient had mild and unchanged.

## ASSOCIATED SYMPTOMS

### 1. *Kati-shroni-vanksanruja* (low back and groin pain):

- Out of 30 total patients, 21 patients had the symptom. After the treatment 8 patients i.e 38.09% showed complete cure, 9 patients i.e. 42.85% had moderate improvement and 4 patients i.e.19.04% showed no improvement.

### 2. *Hrit-parsa-pristharuja* (upper back pain):

- Out of 30 total patients, 12 patients had the symptom. After the treatment only 1 patient i.e 8.33% showed complete cure, 11 patients i.e. 91.66% had mild improvement. No patient remains unchanged after treatment.

### 3. *Daha* (burning sensation):

- Out of 30 total patients, 10 patients had the symptom. After the treatment 7 patients i.e.70% had complete cure and 3 patient i.e.30% patients had mild improvement. No patient remains unchanged after treatment.

### 4. *Jwara and bhrama* (fever and dizziness):

- No patient showed this symptom.

### 5. *Arochak* (loss of appetite):

- No patient showed this symptom.

### 6. *Chardi* (vomiting and nausea):

- No patient showed this symptom.

## CONCLUSION

- The health of nation mainly depends upon the health of women because the healthy and happy women lay the first step of a prosperous nation.
- The Drugs *Kutajastaka* pacifying pitta by their *tikta*, *kashaya rasa* and *vata* by their *ushnaveerya*. Along with these gunas they have additional *Raktashodhak*, *Raktastambhaka*, *Sothahara* and *raktapitta hara* property by which these drugs causes *samprapti vighatan* of *Asrigdara*. It is also proven by modern researches that most of the drugs used in *kutajstaka* have anti-inflammatory, antioxidant and vascular stabilizing property.
- The drug showed encouraging result in symptoms associated with *asrigdara* without having any untoward effect in the patients.
- It has shown to be effective in excessive and prolong bleeding by reducing both amount and duration of blood loss, normalising intermenstrual period and also relieved pain
- It is hoped that the results of this research well estimate the thinking of the ayurvedic scholars interested in this field to find out a care for this disorder and thus ayurveda may contribute in the relief to the suffering humanity and glory of the science can be maintained.

## RECOMMENDATION FOR FURTHER STUDY:

- 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 *Asrigdara*.
- The Trial drug "*KUTAJASTAKA*" with a short span of research with limited facilities have given an impression that the research drug is very effective in *Asrigdara*

(Dysfunctional uterine bleeding).Hence, the long-term benefits of the drug should be evaluated.

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