

MANAGEMENT OF ASRIGDARA WITH KUTAJASHTAKA AVALEHA AND YASHTIMADHU GHRITA MATRA BASTI - AN OPEN LABEL, DOUBLE ARM, RANDOMIZED CLINICAL TRIAL

[Stuti Sharma](#)¹, [Meenakshi Pandey](#)²

¹M.S. (Ayu.) Scholar, ²Assistant Professor

Department of Stri Roga and Prasuti Tantra, All India Institute of Ayurveda, Sarita Vihar, New Delhi, India

Corresponding Author: stuti.sharma0904@gmail.com

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ABSTRACT

Introduction: The word *Asrigdara* explains about prolonged, cyclic or acyclic excessive menstrual bleeding in *Ayurveda*. 9-14% of women in their reproductive age lose 80 ml of blood in each cycle. It is the most common cause of Anemia. Traditionally, Heavy Uterine Bleeding is managed with medical therapy and surgical intervention with associated side effects. But due to limitation of medical therapy as well as surgical interventions, it becomes the necessity of time to find out a permanent, easy, effective and less side effect producing care which can be easily administered and accepted by the patient. **Objective:** To evaluate the clinical efficacy of *Kutajashtaka Avaleha* orally and combination of *Kutajashtaka Avaleha* and *Yashtimadhu Ghrita matra basti* in combating the signs and symptoms of *Asrigdara*. **Materials and Methods:** 56 patients were selected from the Stri Roga and Prasuti Tantra OPD, All India Institute of Ayurveda, New Delhi and randomly divided into 2 groups. Group A was administered with *Kutajashtaka Avaleha* orally regularly for the period of 3 months with the doses of 5gm BD after meal with water, while in Group B, Combination of *Yashtimadhu Ghrita Matra Basti* (60 ml for 7 days in 3 consecutive cycles after meal through rectal route after 7th day of menses) for 3 months and *Kutajashtaka Avaleha* was given and the follow up period of 1 month without medication was same for both the groups. **Results:** *Kutajashtaka Avaleha* orally alone and Combination of *Yashtimadhu Ghrita Matra Basti* & *Kutajashtaka Avaleha* oral both gave statistically highly Significant results ($P < 0.001$) but with better results when the treatment was combined and Markedly

Improved (51-75% relief) the signs and symptoms. **Conclusion:** Combination of *Yashtimadhu Ghrita Matra Basti* & *Kutajashtaka Avaleha* oral gave more statistically significant results than *Kutajashtaka Avaleha* orally alone. No adverse effects were reported during the entire trial period.

Keywords: *Ayurveda, Asrigdara, Kutajashtaka Avaleha, Matra Basti, Yashtimadhu Ghrita.*

INTRODUCTION

28% of the female population consider their menstruation excessive and will plan their social activities around their menstrual cycle¹. 9-14% of women in their reproductive age lose 80 ml of blood in each cycle. In its multiple country study, World Health Organization (WHO) identified the prevalence of three-month severe bleeding as 8-27%². If the menstrual cycle turns to be abnormal with excessive and prolonged bleeding associated with pain or appearing at irregular intervals is suggestive of some underlying pathology. It is the most common cause of Anemia and Dysmenorrhea³. *Asrigdara* is one amongst extensive range of occurrence. The word *Asrigdara* explains about prolonged, cyclic or acyclic excessive menstrual bleeding in *Ayurveda*⁴. Acharya *Sushruta* has said that Prolonged and excessive menstrual bleeding along with Pain and Body ache are the clinical features of *Asrigdara*⁵. *Asrigdara* is a symptom of various *Yonivyapadas* including *Pittaja Yonivyapad, Asrija Yonivyapad, Lohit-kshara Yonivyapad, Paripluta Yobivyapad and Rakta-yoni and Artava-dushti* including *Kunapa-Gandhi and Pittaja Artava-dushti*. It is also related to *Parisravi Jatharini and Raktarbuda*. It is a *Rakta-Pradoshaja Vikara* due to *Pittavritta ApanaVayu* causes vitiation of *Rakta-Dhatu*⁶. *Ashtanga Sangraha* has explained *Raktayoni* and said *Asrigdara* and *pradara* as its synonyms⁷. Traditionally, heavy Uterine Bleeding is managed with medical therapy with associated side effects and if unsuccessful is followed by surgical intervention⁸. Therefore, it becomes the necessity of time to find out a permanent, easy, effective and less side effect producing care which can be easily administered and accepted by the patient. So many preparations have been mentioned in our texts for the treatment of *Asrigdara*. These are *Pitta-Kapha shamaka and shodhaka, Raktashodhaka and stambhaka, Garbhashaya Balya and Vatanulomana. Samprapti Vighatana* and effective control and

cure in the *Asrigdara* are the main aims with which the drugs were selected for the present study. No previous work is done on these two formulations. So, formulations namely *Kutajashtaka Avaleha*⁹ and *Yashtimadhu Ghrita Matra Basti*¹⁰ have been selected to work upon. **Objective-**To evaluate the clinical efficacy of *Kutajashtaka Avaleha* orally and combination of *Kutajashtaka Avaleha* and *Yashtimadhu Ghrita matra basti* in combating the symptoms of heavy and prolonged menstrual bleeding or intermenstrual bleeding in cases of *Asrigdara*.

Materials

Preparation of Trial drug-All the drugs were collected and authenticated from reliable sources and standardization was done as per API guidelines. *Kutajashtaka Avaleha* and *Yashtimadhu Ghrita* were made in GMP certified Pharmacy. **Selection of route of administration of drug-** *Basti therapy* is the best treatment for *Vikrita Apanavayu* and *Artavavikara*. Thus, it normalizes the functions of different *Srotasa* as it clears the obstruction and allows freely movement of bioenergetics through the channels. Thus, it acts as curative, rejuvenative and preventive measure. It cures all kinds of diseases due to its varied pharmacodynamics and various kinds of drugs used in its preparation. **Ethical approval-**The clinical trial was approved by the Institutional Ethics Committee of All India Institute of Ayurveda, Sarita Vihar, New Delhi. (IEC-AIIA/2018-PG-104). **Trial Registration-**Study was registered in Clinical Trials Registry of India. (CTRI/2019/08/020743)

Methods

Study Design-An open labelled, double arm, interventional, prospective randomized clinical trial of sample size 56 with duration 3 months.

Selection of Patients-Total 56 patients were selected from the SRPT OPD, AIIA, New Delhi and randomly

divided into 2 groups. Patients were selected on the basis of symptoms – Heavy and prolonged menstrual bleeding or intermenstrual bleeding.

Informed Consent: The purpose of the study, nature of the selected drugs, the procedures to be carried out and the potential risks and benefits were explained to the patients in detail in non- technical terms and bilingual. Thereafter their written consent was taken before the treatment. A suitable **case report form (CRF)** was filled for the specific assessment outline and entered in electronic format designed in Microsoft Excel.

Inclusion Criteria-(i) Women of reproductive age group 18-45years, (ii) Patients with symptoms of heavy and prolonged menstrual bleeding or intermenstrual bleeding, (iii) Patients who were interested and gave their written consent for the study work, (iv) Patients who were willing to go for relevant investigations. **Exclusion Criteria-**(i) Patients with any diagnosed uterine organic pathology like Uterine Fibroid, Adenomyosis, chronic Tubo-ovarian mass. (ii) Patients with systemic diseases like hypertension, diabetes mellitus, congestive cardiac failure etc. (iii) Patients with coagulopathy, liver and thyroid dysfunction etc. (iv) Patients with malignancy or undiagnosed neoplasm. (v) Patients with

history of recent abortion. (vi) patients with active genital tuberculosis. (vii) Bleeding from the polyps and erosion. (viii) IUCD in utero, pelvic endometriosis. (ix) Hb< 8 gm/dl. (x) Patients with history of chronic constipation.

Diet - Diet pattern was same for both the groups. Patients were advised to take routine diet and to avoid excessive oily, sweet, spicy, fried food, curd, fermented food, over diet and sour items. To consume more green vegetables, fruits and milk.

Grouping and Drug delivery regimen-Equal number of samples were taken in two groups by randomization. Group A was administered with *Kutajashtaka avaleha* orally regularly for the period of 3 months with the doses of 5gm BD after meal with water. Group B was administered with the combination of *Kutajashtaka avaleha* and *Yashtimadhu Ghrita matra basti* (60 ml for 7 days in 3 consecutive cycles after meal through rectal route after 7th day of menses) for 3 months.

Outcome Measures-

Criteria for assessment (Subjective parameters)-(i) Duration of bleeding. (ii) Inter menstrual period. (iii) Lower abdominal pain. (iv) Low backache. (v) Amount of blood loss.

Table 1: Grading of the subjective parameters

Subjective Parameters	Grade 0 (Normal)	Grade 1 (Mild)	Grade 2 (Moderate)	Grade 3 (Severe)
Duration of bleeding	Less than 5 days	5-7 days	8-10 days	Greater than 10 days
Intermenstrual period	26-30 days	21-25 days	16-20 days	Less than 15 days/Irregular
Lower Abdominal pain	0 (No pain)	1-3 in VAS (Mild pain)	4-7 in VAS (Moderate pain)	8-10 in VAS (Severe pain)
Low Backache	0 (No pain)	1-3 in VAS (Mild pain)	4-7 in VAS (Moderate pain)	8-10 in VAS (Severe pain)

Amount of Blood loss (Menstrual Pictogram)¹¹

TOILETS	Score	CLOTS	Score	TOWELS	TYPE	Score
	1ml		1ml		Day time	1ml
	3ml		3ml		Night time	1ml
	5ml		5ml		Day time	2ml
					Night time	3ml
					Day time	3ml
					Night time	6ml
					Day time	4ml
					Night time	10ml
					Day time	5ml
					Night time	15ml

Table 2: A numerical scoring system was devised to coincide with the amount of blood lost in Menstrual Pictogram

	Remarks	Light	Moderate	Heavy
Toilets	Volume of blood lost in the toilet when changing sanitary wear.	1(1ml)	3(3ml)	5(5ml)
Clots	Amount of Blood lost in the form of Clots	1(1ml)	3(3ml)	5(5ml)
Towels	Amount of Blood soaked in the towel/Sanitary Pad.	1(1ml)	5(5ml)	20(20ml)

Matra Basti Assessment parameters¹²- *Samyak Yoga, Ayoga and Atiyoga Lakshanas* of *Matra basti* were assessed in 3 consecutive cycles. *Matra Basti* was performed in following three steps- *Poorva karma- Local Abhyanga* with *Bala taila* for 20 minutes followed by *Swedana* by *Nadi sweda* for 20 minutes. *Pradhan Karma-* slowly and steadily 60 ml *Yashtimadhu Ghrita* was administered through rectal route with plastic syringe and rubber catheter and patient was asked to inhale and exhale deeply and keep her as relaxed as possible. *Pashchata Karma-* patient was tapped on the back and legs were bent, asked her to lie down supine for at least 15 minutes and hot water bag was given for *Swedana* purpose. **Statistical Analysis-**The SPSS statistical software was used for statistical analysis. The mean, standard deviation, standard error will be calculated for each group. Statistical analysis was done by applying 'Unpaired t-test' to BT and AT assessment scores. Mean % reduction in subjective parameters for

both the groups was calculated and Obtained results were measured according to the grades as Complete remission 100%, marked improvement 76-99%, moderate improvement 51-75%, mild improvement 26-50% and no improvement <25% relief in the sign and symptoms.

Observations and Results

Status of enrolled patients: Total diagnosed 62 patients having Sign and symptoms of *Asrigdara* were registered for the clinical trial, out of which 56 patients (28 patients in each group) completed the clinical study with follow up and 6 patients (2 in Group A and 4 in Group B) discontinued the treatment due to personal reasons.

Demographic Profile: Demographic data of enrolled patients (n = 56) viz. distribution of patients according to age, marital status, educational status, socio-economic status, occupation, habitat and religion are depicted in Table 3.

Table 3: Demographic Data of enrolled patients-

Data	Criteria	N=56	Percentage
Age	18-26 yrs	10	17.86%
	27-36 yrs	21	37.50%
	37- 45 yrs	25	44.64%
Marital status	Married	48	85.71%
	Unmarried	7	12.59%
	Widow	1	1.79%
Educational status	Uneducated	9	16.07%
	Primary	7	12.50%
	Secondary	18	32.14%
	Higher secondary	15	26.78%
	Graduation	6	10.72%
	Post-Graduation	1	1.79%
Socio-economic status	Lower middle	21	37.50%
	Middle	27	48.21%
	Upper middle	5	8.93%
	Rich	3	5.36%
Occupation	Housewife	39	69.64%
	Working/Job	17	30.36%
Habitat	Rural	13	23.21%
	Urban	43	76.79%
Religion	Hindu	50	89.28%
	Muslim	6	10.72%

Present Menstrual history- 66.07% had regular cycle and 33.93% had irregular cycle. 58.93% patient had moderate blood loss and 41.07% were having excessive blood loss. 66.07% patient had interval of menstrual period 16-20 days and 62.5% were having painless menses.

Chief Complaints-Duration of Bleeding: 53.57% were having duration of bleeding for 8-10 days, while each 23.21% were having 5-7 days and greater than 10 days respectively.

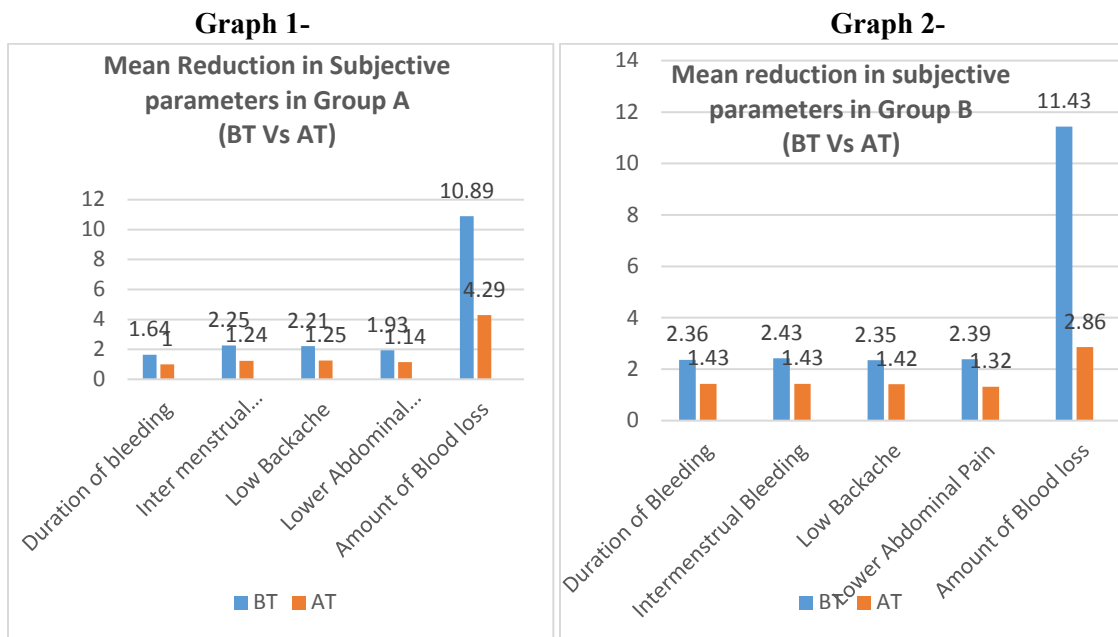
Intermenstrual Period: 66.07% were having their intermenstrual period of 16-20 days and 33.93% were having less than 15 days or irregular intermenstrual period.

Lower abdominal pain: 58.93% were having moderate lower abdominal pain and 28.57% were having severe lower abdominal pain.

Low Backache: 60.71% were having moderate low backache, 33.93% were having severe backache.

Amount of blood loss: 58.93% were having moderate bleeding during their menstruation and 41.07% were having heavy bleeding during their periods. 53.57% were having heavy clots during their menses.

Effect of Therapy- Graph 1 & Graph 2 showing mean reduction in subjective parameters in group A and group B respectively, depicted here-



Effect of therapy on subjective parameters (between the groups)-

Duration of bleeding: When compared between the two groups, mean difference of duration of bleeding from BT to AT in group B is 0.93, which is greater than group A i.e. 0.64 with mean difference of -0.29. It reveals that Duration of bleeding is significantly reduced in group B as compared to group A and it was found statistically significant ($t=2.44$, $df=54$, $p<0.05$).

Intermenstrual period: When compared between the two groups, mean difference of Intermenstrual period from BT to AT in group B is 0.36, which is greater than group A i.e. 0.04 with mean difference of -0.32. It reveals that Intermenstrual bleeding is significantly reduced in group B as compared to group A and it was found statistically significant ($t=3.25$, $df=54$, $p<0.05$).

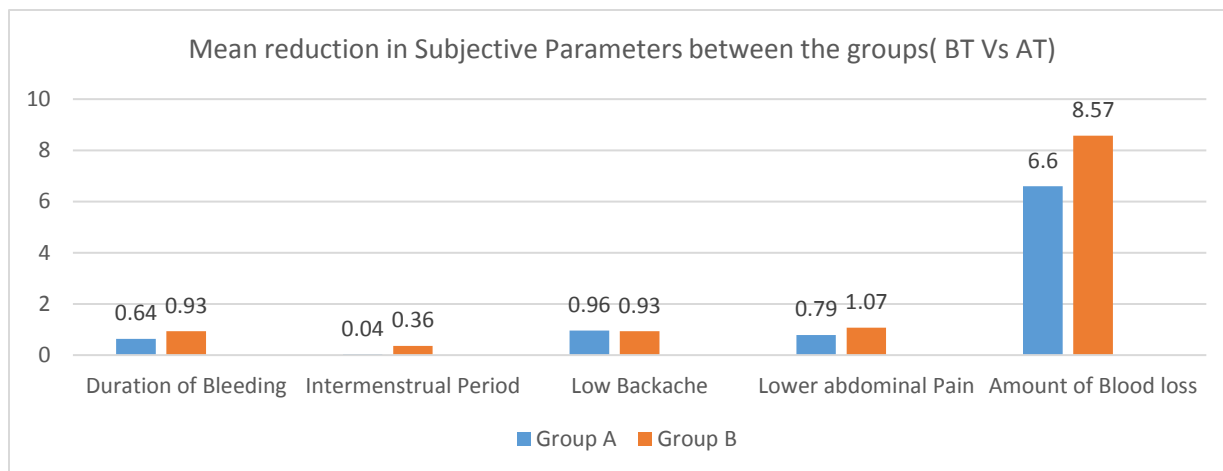
Lower Abdominal pain: When compared between the two groups, mean difference of lower abdominal pain

from BT to AT in group B is 1.07, which is greater than group A i.e. 0.79 with mean difference of -0.28. It reveals that Lower abdominal pain is significantly reduced in group B as compared to group A and it was found statistically significant ($t=2.41$, $df=54$, $p<0.05$).

Low backache: When compared between the two groups, it was observed that with reference to low backache, treatment given in both the respective groups is equally effective and therefore none of the 2 group is superior. ($t=0.38$, $df=54$, $p>0.05$).

Amount of blood loss: When compared between the two groups, Mean difference of amount of blood loss from BT to AT in group B is 8.57, which is greater than group A i.e. 6.60 with mean difference of -1.96. It reveals that Amount of blood loss is significantly reduced in group B as compared to group A and it was found statistically significant ($t=1.15$, $df=54$, $p<0.05$).

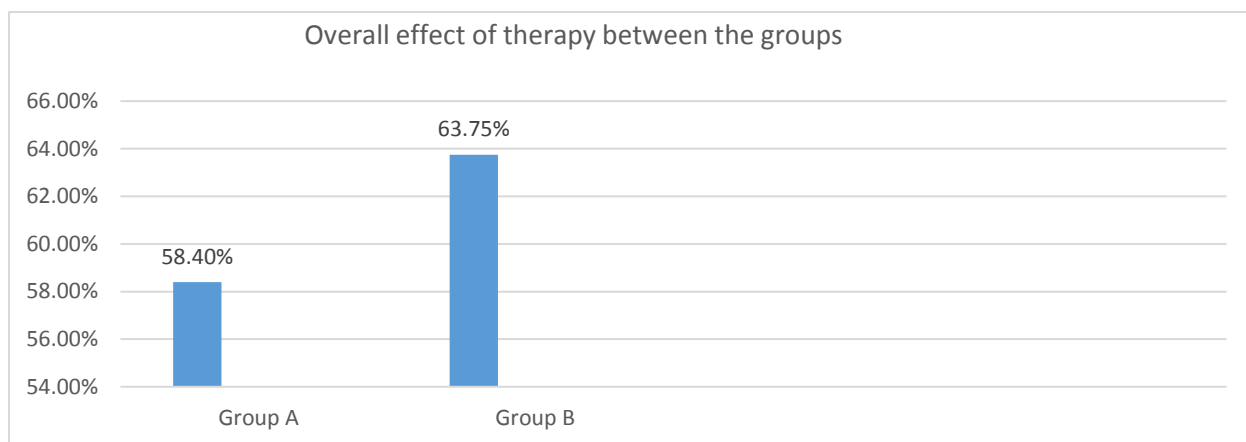
Graph 3: Mean reduction in subjective parameters (Between the groups)- BT vs AT



Overall Effect of therapy (By Calculating mean of % reduction in all 5 subjective parameters)- Group A- 58.40%, Group B-63.75%- It is clearly seen that the

treatment given to the patients in both the Groups has Markedly Improved (51-75% relief in sign and symptoms) the signs and symptoms of *Asrigdara*.

Graph 4: Overall effect of therapy between the groups (BT vs Follow up)



DISCUSSION

Asrigdara is a disease manifesting as excessive bleeding per vaginum. The majority of the *Lakshanas* of *Asrigdara* are due to *aggravated Vayu*, withholding the *Rakta* (blood) & *Pitta* vitiated due to *Nidana Sevana* (*Ahara, Vihara & Manosambandhi Nidana*), increases its amount and then reaching *Raja* carrying vessels (branches of ovarian and uterine arteries) of the uterus, increases immediately the amount of *Raja* (*Artava* or menstrual blood). Vitiation of *Tridosha* leads to *Agnimandyata* which leads to *Vikrit Ahara Rasa Nirmana* and *Rasagni Vaishamyia* & due to this *Vikrit Rasa Dhatu Nirmana* takes place. *Artava* being *Upadhatu* of

Rasa is also vitiated and because of this *vikrit artava pramana vridhhi* occur which affect the *Garbhashaya-gataSira* (Uterine Congestion/ Increased uterine circulation) which leads to *Apana Vayu Dushti* and *Atyadhik and Chiarakala Artavastrava (Asrigdara)*¹³. The general principles of treatment of bleeding per vaginum as follows- *Dosha Shodhana* and *Shamana, Rakta-Sthapana & Sangrahana*, Use of *Tikta Rasa* and Eradication of the cause¹⁴. Considering this principle of treatment, *Kutajashtaka Avaleha* and *Yashtimadhu Ghrita Matra Basti* has been selected for the clinical trial. Both the formulations have *Deepana, Pachana, Rakta-Sthapana and Rakta-Sangrahana, Kashaya, Tikta and Madhura*

Rasa, Garbhashaya Balya, Vatanulomana, Shothahara and Grahi effect. Basti therapy is considered as Prime among all the therapeutic measures specially for the management of Vata-Vyadhies. Our Acharyas have considered the Guda (rectum) as the root of the body (Shariramoola). On the action of Basti, Vagabhata says that Virya of Basti is conveyed to Apana and then to Samana Vata, which may regulate the function of Agni. It then goes to Udana, Vyana and Prana, thus providing its efficacy all over the body. At the same time Basti by pacifying Vata, restores the disturbed Kapha and Pitta at their original seats and thus helps in breaking the pathogenesis. Yashtimadhu Ghrita was used for Matra basti. Yashtimadhu (*Glycyrrhiza glabra*) is having Madhura Vipaka, Sheeta Virya, Madhura Rasa, Shothahara and Garbhashaya Balya properties¹⁵. Ghrita alleviates vata, pitta and toxic conditions from the body. It is the best of all the unctuous substances. It is having sheeta virya, madhura rasa and madhura vipaka. Old Cow ghee is useful in intoxication as well as for disorders of female genital tract¹⁶.

Effect of therapy on Subjective parameters-

Duration of Bleeding: Kutaja, Mochrasa, Ativisha, Dhataki and Bilva have Upshoshana, Grahi and Stambhana properties & Madhura Rasa of Yashtimadhu and Ghrita, which alleviates Vata and Pitta hereby reducing the duration of bleeding.

Intermenstrual period: Most of the Drugs having deepana, pachana property which improves the status of Agni and correct Agnimandyata. Kutaja, Mochrasa, Ativisha, Bilva and Dhataki have Upshoshana, Grahi and Stambhana properties¹⁷, so it has reduced the intermenstrual bleeding. Sheeta Virya of Yashtimadhu and Ghrita pacifies Pitta dosha which is responsible for repeated and intermenstrual bleeding.

Low Backache & Lower Abdominal Pain: It was due to Analgesic Property of Kutaja, Mochrasa & Musta help in alleviating the Low Backache and Lower Abdominal Pain. Aggravated Vata Dosha (which causes vitiation of rakta & pitta) is pacified by Snigdha and Guru guna of Madhura rasa (Yashtimadhu and Ghrita), hence reducing the Low Backache and Lower abdominal pain.

Amount of Blood Loss: Anti-inflammatory property

of Yashtimadhu reduces the Amount of blood loss by reducing the congestion in uterine vessels¹⁸. Patha, Lajjala and Musta have Shodhana and Shothahara properties so it has reduced the amount of blood loss by reducing the congestion in uterine vessels¹⁹.

CONCLUSION

Kutajashtaka Avaleha orally alone and Combination of **Matra Basti** with **Yashtimadhu Ghrita & Kutajashtaka Avaleha** oral both gave highly Significant results ($p < 0.001$) in the management of **Asrigdara** with better results when the treatment was combined. Treatment given to the patients in both the Groups has markedly improved (51- 75% relief) the signs and symptoms of **Asrigdara**. Overall effect of therapy between the Groups revealed that the Mean % reduction in all the five subjective parameters in Group B was more (63.75%) as compared to Group A (58.40%). **Matra Basti** also helped in regularization of **Apana Vayu**, thereby normalizing the flow of menstrual blood. **Basti** by pacifying **Vata**, restores the disturbed **Kapha** and **Pitta** at their original seats and thus helps in breaking the pathogenesis. On comparing the effect between the two groups, it can be concluded that the combination of **Kutajashtaka Avaleha** and **Yashtimadhu Ghrita Matra Basti** was found statistically more significant as compared to **Kutajashtaka Avaleha** given alone. No adverse effects were reported during the entire study period by any of the patients in either of the Group.

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