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EFFECT OF LAJJALU GHANA VATI IN ASRIGDARA-A CLINICAL STUDY

Dr. Harshitha Vasundhara P.*[1] and Dr. Sunita Siddesh[2]

[1]PG Scholar, Dept. of PG Studies in PTSR, SKAMCH and RC, Bangalore, Karnataka, India.

[2]Professor and HOD, Dept. of PG Studies in PTSR, SKAMCH and RC, Bangalore, Karnataka, India.

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***Corresponding Author**
Dr. Harshitha Vasundhara P.
Final Year PG Scholar, Dept. of PTSR, Sri Kalabyaraveshwara Ayurvedic Medical College Hospital and Research Center, Bangalore-560104, Karnataka, India.

ABSTRACT

The word "Stree" relates to her capacity of fertilization. Apart from social and professional commitments a woman is committed to her role as wife and mother. This added strain in her physical and psychological framework can prove deleterious unless proper care is taken. The weak link in this chain and the one which is most likely to get disturbed is the menstrual rhythm and the fertility. Asrigdara is a broad term and includes most of the diseases with cardinal symptom of excessive per vaginal bleeding. It is highly prevalent gynaecological disease and can be co-related to Dysfunctional uterine bleeding. As Asrigdara is a debilitating disorder disturbing her daily routine, the woman requires safe and effective treatment. Ayurvedic texts have described a variety of treatment options in the management of "Asrigdara". So, the present study is under taken to evaluate the efficacy of Lajjalu Ghana Vati.

KEYWORDS: Lajjalu Ghana Vati, Asrigdara, Clinical Study.

INTRODUCTION

Stree has been given prime or special status in India from times immemorial. Woman is endowed with energy of procreation for which menarche is the first step. Menstrual cycle commences with this & ends with menopause & having normal menstruation depicts the well being of female. A slight deviation in the menstrual cycle which may be excessive or low is leading to the fear of some serious pathology of internal genital organs. Women of today commonly experiencing heavy menstrual bleeding due to small family size, early menarche,

later onset of menopause & increased responsibilities due to changing role of women in society. Thus the increased stress disturbs the delicate rhythm of endocrine system in female, resulting in variety of disorders. Asrigdara characterized by excessive prolonged menstrual or intermenstrual bleeding[1] & it is described at around 1400BC, which has been described in ancient literature. Though such vast explanation is given yet efforts are required to identify them clinically & establish their occurrence. This condition is distressing & potentially disabling, with this social & work commitments being cancelled. Acharya Charaka described Asrigdara elaborately under Yoni Vyapad chikitsa adhyaya.[2] Acharya Vagbhata has mentioned classification and clinical features of Asrigdara in detail.Acharya Susruta opines that – Artava in excess amount and for prolonged period, as well as during intermenstrual period even if scanty and for short duration should be termed Asrigdara.[3]

Acharya Charaka further opines -Atiprasangena – excess menstruation (Atimatra + Deerghakalanubandhi), Pravruttam anrutavapi – bleeding in intermenstrual period, even if scanty & for short duration. Anyad rakta lakshanam – features different from normal menstruation i.e., doshanubandhi. Other lakshanas: angamarda, samvedana, achirena ghoran arti in adhovanmkshana desha, shroni, prushta, kukshi & garbhashaya.[4] Due to nidana sevana,vayu gets vitiated which inturn vitiates rakta, where the amount of rakta increases then reaches the rajovaha siras, thereby increasing the amount of raja. Since there is excessive flow in amount of raja/asrig, it is named as Asrigdara.[5] As the ksheera nadi gets filled with Vata in Vandhya, she suffers from adhika Arthava.[6] In Ayurvedic classics treatment is mentioned to keep the doshas in equilibrium. It can be achieved by Samshodhana[7] – Cleansing process which is in form of Panchakarma. Samshamana – Palliative measures which is in form of *Raktasthambhaka dravyas*. Hence for the present study shamana line of treatment is selected as the medicines are easilyavailable, are palatable & cost effective. For the treatment of Asrigdara many drugs are available, among them "Lajjalu[8]" in the form of Ghana Vati has been selected for oral administration.

Objective of the study

To evaluate the efficacy of *Lajjalu Ghana Vati* in the management of *Asrigdara.*

Methodology

The current study "EFFECT OF *LAJJALU GHANA VATI* ON *ASRIGDARA* - A

CLINICAL STUDY" was carried out on 20 patients attending the OPD and IPD of *Prasooti-Tantra evam StreeRoga* department, SKAMCH &RC Bangalore. The sample collection was initiated post approval, from the Institutional Ethical Committee.

Diagnostic criteria

- Patients having *pratyatmalakshanas* of *Asrigdara.*
- Patients having bleeding per vagina for more than 7 days.

Inclusion criteria

- Patients aged between 20 to 50 years.
- Patients with *pratyatmalakshanas* of *Asrigdara*
- H/o excessive bleeding for at least 2 menstrual cycles.

Exclusion criteria

- Patients with any systemic disorders which interfere with the course of treatment.
- Patients using intrauterine contraceptive device.

Assessment Criteria

Signs and symptoms were assessed using the following subjective and objective parameters- Amount of Bleeding, Duration of Bleeding, Intermenstrual period, Consistency of Bleeding, Pain in lower abdomen, Body ache, Low backache, Giddiness, Weakness, Pallor and Thirst.

Investigations

Hb %

USG-Abdomen & Pelvis

Bleeding time

Clotting Time

INTERVENTION

A clinical study with pre and post test design was conducted on 20 randomly selected patients of *Asrigdara* were administered *Lajjalu Ghana vati* 500mg 2 *vati*, thrice a day with *jala*, before food for 2 consecutive menstrual cycles.

Follow up: Next 2 Mentrual Cycles

Preparation of Drug

Preparation of *Lajjalu Ghana Vati* was according to *Ghana Vati* preparation explained in *Sharangadhara Samhitha.*[9]

Ingredients

1. *Lajjalu* Leaves, stem and root- 8kgs (1 part)
2. *Jala*- 64litres (8 parts)
3. Ghee for rolling pills- q.s

Preparation of *Lajjalu Ghana Vati*.

The physical impurities of *Lajjalu* were removed. *Lajjalu* was made into pieces of 1-2 inches. Pieces of *lajjalu* were added to eight times of potable water in a Stainless Steel vessel. This was kept for boiling over low flame with intermittent stirring. Boiling was continued till it is reduced to 1/4th and this *kwatha* was filtered through four fold cotton cloth. Filtered *Lajjalu Kwatha* was subjected to heat with constant stirring till the entire mass converted into semi solid state. The mass was shifted into a tray, allowed to cool. The mas was rolled into vati of 500 mg each and kept in shade for complete drying. After complete drying it was collected and packed in air tight container.

Total Duration of study: 120 days.

- Before treatment (BT): First day of treatment.
- During treatment 1 (DT1): First cycle of menses during treatment.
- During treatment 2 (DT2): Second cycle of menses during treatment.
- 1^{st} follow up (AF1):- 1^{st} cycle of menses after treatment.
- 2^{nd} follow up (AF2):- 2^{nd} cycle of menses after treatment.

Clinical Assessment

Observations: Various parameters like Age, Religion, Occupation, Education, Socio economic status, Marital status, Habitat, Dietary Habit, Rasa, Bowel habit, Sleep, Dashavidha Pareeksha, other parameters like Consistency of Menstrual blood, Pain in Lower Abdomen, Duration of Bleeding, Duration of illness, interval between bleeding in patients.

Assessment criteria

The results of the treatment were assessed on the basis of assessment and analysis was done using Chi square test and student's 't' test as follows:

ASSESMENT PARAMETERS

1. Amount of Bleeding(Assessment by Pad).

Normal – 2-3 pads/day	0
Mild – 4 – 5 pads/day	1
Moderate – 6– 7 pads/day	2
Severe – more than 7 pads/day	3

2. Duration of Bleeding.

Normal – 2-5 days	0
Mild – 6 –10 days	1
Moderate – 11 – 15days	2
Severe – more than 15 days	3

3. Intermenstrual period.

Normal – 28 -35 days	0
Frequency – once in 20 days	1
Frequency – once in 10-15 days	2
Continuous flow or with a gap of 1-2 days	3

Sl No.	Symptoms	Present(P)	Absent(A)
4.	Body Ache	P	A
5.	Pain in lower abdomen	P	A
6.	Consistency of Bleeding	P	A
7.	Low backache	P	A
8.	Giddiness	P	A
9.	Weakness	P	A
10.	Pallor	P	A
11.	Thirst	P	A

Statistical Interpretation

Interpretation	p-value-	p-value- t test
Non significant	>0.05	>0.05
Significant	< 0.05	<0.05,<0.01
Highly significant	<0.01, <0.001	<0.001

OBSERVATIONS AND RESULT

1. Effect of treatment on amount of bleeding.

Group	Mean		Mean diff	Paired t- Test				
	Before	After		SD	SE	t- value	p-value	Remarks
BT-DT1	1.85	1.55	0.3	0.47	0.10	2.85	<0.01	S
BT-DT2	1.85	1	0.85	0.58	0.13	6.47	<0.001	HS
BT-AF1	1.85	0.65	1.2	0.69	0.15	7.70	<0.001	HS
BT-AF2	1.85	0.1	1.75	0.71	0.16	10.91	<0.001	HS

2. Effect Of Treatment on Duration of Bleeding.

Group	Mean		Mean diff	Paired t- Test				
	Before	After		SD	SE	t- value	p-value	Remarks
BT-DT1	1.75	1.25	0.5	0.60	0.13	3.68	<0.01	HS
BT-DT2	1.75	0.9	0.85	0.67	0.15	5.66	<0.001	HS
BT-AF1	1.75	0.75	1	0.64	0.14	6.88	<0.001	HS
BT-AF2	1.75	0.1	1.65	0.74	0.16	9.89	<0.001	HS

3. Effect of Treatment On Interval Between Bleeding.

Group	Mean		Mean diff	Paired t- Test				
	Before	After		SD	SE	t- value	p-value	Remarks
BT-DT1	1.7	1.3	0.4	0.50	0.11	3.55	<0.01	HS
BT-DT2	1.7	1	0.7	0.57	0.12	5.47	<0.001	HS
BT-AF1	1.7	0.7	1	0.79	0.17	5.62	<0.001	HS
BT-AF2	1.7	0.15	1.55	0.60	0.13	11.45	<0.001	HS

4. Effect of Treatment on Consistency of Bleeding.

Group	Mean		Mean diff	Paired t- Test				
	Before	After		SD	SE	t- value	p-value	Remarks
BT-DT1	1.65	1.2	0.45	0.60	0.13	3.32	<0.01	HS
BT-DT2	1.65	1	0.65	0.74	0.16	3.89	<0.001	HS
BT-AF1	1.65	0.75	0.9	0.78	0.17	5.10	<0.001	HS
BT-AF2	1.65	0.1	1.55	0.68	0.15	10.09	<0.001	HS

5. Effect of Treatment on Lower Abdominal Pain.

BEFORE TREATEMENT – DURING TREATMENT 1					
Phase	Present	Absent	χ2 Value	p-value	Remarks
BT	20	0	3.24	>0.05	NS
DT1	17	3			
BEFORE TREATEMENT – DURING TREATMENT 2					
Phase	Present	Absent	χ2 Value	p-value	Remarks
BT	20	0	5.7	<0.05	S
DT2	15	5			
BEFORE TREATEMENT – FOLLOW UP 1					
Phase	Present	Absent	χ2 Value	p-value	Remarks
BT	20	0	17.14	<0.001	HS
AF1	8	12			
BEFORE TREATEMENT – FOLLOW UP 2					
Phase	Present	Absent	χ2 Value	p-value	Remarks
BT	20	0	26.66	<0.001	HS
AF2	4	16			

6. Effect of Treatment on Body Ache.

BEFORE TREATEMENT – DURING TREATMENT 1					
Phase	**Present**	**Absent**	**χ2 Value**	**p-VALUE**	**Remarks**
BT	20	0	4.44	<0.05	S
DT1	16	4			
BEFORE TREATEMENT – DURING TREATMENT 2					
Phase	**Present**	**Absent**	**χ2 Value**	**p-value**	**Remarks**
BT	20	0	13.32	<0.001	HS
DT2	10	10			
BEFORE TREATEMENT – FOLLOW UP 1					
Phase	**Present**	**Absent**	**χ2 Value**	**p-value**	**Remarks**
BT	20	0	21.52	<0.001	HS
AF1	6	14			
BEFORE TREATEMENT – FOLLOW UP 2					
Phase	**Present**	**Absent**	**χ2 Value**	**p-value**	**Remarks**
BT	20	0	32.72	<0.001	HS
AF2	2	18			

7. Effect of Treatment on Low Back Ache.

BEFORE TREATEMENT – DURING TREATMENT 1					
Phase	**Present**	**Absent**	**χ2 Value**	**P-value**	**Remarks**
BT	20	0	3.24	>0.05	NS
DT1	17	3			
BEFORE TREATEMENT – DURING TREATMENT 2					
Phase	**Present**	**Absent**	**χ2 Value**	**P-value**	**Remarks**
BT	20	2	11.6	<0.001	HS
DT2	11	9			
BEFORE TREATEMENT – FOLLOW UP 1					
Phase	**Present**	**Absent**	**χ2 Value**	**P-value**	**Remarks**
BT	20	0	17.14	<0.001	HS
AF1	8	12			
BEFORE TREATEMENT – FOLLOW UP 2					
Phase	**Present**	**Absent**	**χ2 Value**	**P-value**	**Remarks**
BT	20	0	21.52	<0.001	HS
AF2	6	14			

8. Effect of Treatment on Giddiness.

BEFORE TREATEMENT – DURING TREATMENT 1					
Phase	**Present**	**Absent**	**χ2 Value**	**P-value**	**Remarks**
Bt	16	4	3.94	<0.05	S
Dt1	10	10			
BEFORE TREATEMENT – DURING TREATMENT 2					
Phase	**Present**	**Absent**	**χ2 Value**	**P-value**	**Remarks**
Bt	16	4	12.12	<0.001	Hs
Dt2	5	15			
BEFORE TREATEMENT – FOLLOW UP 1					
Phase	**Present**	**Absent**	**χ2 Value**	**P-value**	**Remarks**

Bt	16	4	19.78	<0.001	Hs
Af1	2	18			
BEFORE TREATEMENT – FOLLOW UP 2					
Phase	**Present**	**Absent**	**χ2 Value**	**P-value**	**Remarks**
Bt	16	4	19.78	<0.001	Hs
Af2	2	18			

9. Effect of Treatment on Weaknessas.

BEFORE TREATEMENT – DURING TREATMENT 1					
Phase	**Present**	**Absent**	**χ2 Value**	**P-value**	**Remarks**
Bt	19	1	2.06	>0.05	Ns
Dt1	16	4			
BEFORE TREATEMENT – DURING TREATMENT 2					
Phase	**Present**	**Absent**	**χ2 Value**	**P-value**	**Remarks**
Bt	19	1	7.02	<0.01	Hs
Dt2	12	8			
BEFORE TREATEMENT – FOLLOW UP 1					
Phase	**Present**	**Absent**	**χ2 Value**	**P-value**	**Remarks**
Bt	19	1	7.02	<0.01	Hs
Af1	12	8			
BEFORE TREATEMENT – FOLLOW UP 2					
Phase	**Present**	**Absent**	**χ2 Value**	**P-value**	**Remarks**
Bt	19	1	28.98	<0.001	Hs
Af2	2	18			

10. Effect of treatment on pallor.

BEFORE TREATEMENT – DURING TREATMENT 1					
Phase	**Present**	**Absent**	**χ2 Value**	**P-value**	**Remarks**
Bt	20	0	2.1	>0.05	Ns
Dt1	18	2			
BEFORE TREATEMENT – DURING TREATMENT 2					
Phase	**Present**	**Absent**	**χ2 Value**	**P-value**	**Remarks**
Bt	20	0	10	<0.01	Hs
Dt2	12	8			
BEFORE TREATEMENT – FOLLOW UP 1					
Phase	**Present**	**Absent**	**χ2 Value**	**P-value**	**Remarks**
Bt	20	0	13.32	<0.001	Hs
Af1	10	10			
BEFORE TREATEMENT – FOLLOW UP 2					
Phase	**Present**	**Absent**	**χ2 Value**	**P-value**	**Remarks**
Bt	20	0	26.66	<0.001	Hs
Af2	4	16			

11. Effect of treatment on thirst.

BEFORE TREATEMENT – DURING TREATMENT 1					
Phase	**Present**	**Absent**	**X2 Value**	**P-value**	**Remarks**
Bt	15	5	2.66	>0.05	Ns
Dt1	10	10			
BEFORE TREATEMENT – DURING TREATMENT 2					
Phase	**Present**	**Absent**	**χ2 Value**	**P-value**	**Remarks**
Bt	15	5	8.1	<0.01	Hs
Dt2	6	14			
BEFORE TREATEMENT – FOLLOW UP 1					
Phase	**Present**	**Absent**	**χ2 Value**	**P-value**	**Remarks**
Bt	15	5	12.12	<0.001	Hs
Af1	4	16			
BEFORE TREATEMENT – FOLLOW UP 2					
Phase	**Present**	**Absent**	**χ2 Value**	**P-value**	**Remarks**
Bt	18	2	25.6	<0.001	Hs
Af2	2	18			

12. Effect of Treatment on Drowsiness.

BEFORE TREATEMENT – DURING TREATMENT 1					
Phase	**Present**	**Absent**	**χ2 Value**	**P-value**	**Remarks**
BT	15	5	5	<0.05	S
DT1	8	12			
BEFORE TREATEMENT – DURING TREATMENT 2					
Phase	**Present**	**Absent**	**χ2 Value**	**P-value**	**Remarks**
BT	15	5	8.1	<0.01	HS
DT2	6	14			
BEFORE TREATEMENT – FOLLOW UP 1					
Phase	**Present**	**Absent**	**χ2 Value**	**P-value**	**Remarks**
BT	15	5	8.1	<0.01	HS
AF1	6	14			
BEFORE TREATEMENT – FOLLOW UP 2					
Phase	**Present**	**Absent**	**χ2 Value**	**P-value**	**Remarks**
BT	15	5	10	<0.01	HS
AF2	5	15			

DISCUSSION

Asrigdara is a disease manifesting as excessive bleeding per vagina. Acharya Charaka and Chakrapani defined deerana of asrik as Asrigdara, whereas Acharya Susruta explained that there will be excessive bleeding during rutu (menstrual) and even slight bleeding during anruta kala (intermenstrual periods) should be treated as Asrigdara. Asrigdara can be correlated to DUB. DUB is defined as a state of abnormal uterine bleeding without any clinically detectable organic, systemic or iatrogenic cause.[10] Agni dushti and rasa dushti leads to improper formation of Artava at different levels i.e., hormonal and endometrium.

The main aim of treatment of Asrigdara is to correct the agni, to correct the srotodushti, to cease the excessive bleeding, maintain general health and prevent complications. Considering these aspects, only such a treatment which can fulfil the basic criteria i.e Raktasthambhaka, Raktapittahara are desired in the treatment as explained in classics.[11] The drug Lajjalu having kashaya, tikta rasa, laghu, ruksha guna, Sheeta veerya, Katu vipaka is kaphapittahara. Ghrita due to its samskaaraanuvartana and yogavahi guna,vata pitta shamaka karmahelps in correcting Apana Vata dushti and Pitta vaishamya.

In Amount of Bleeding, The effect of treatment before Treatment to During.

Treatment1, the p value (< 0.01) revealed statistically Significant, Before Treatment to During Treatment 2, Before Treatment to Follow Up1 and Before Treatment to Follow Up 2, the p value (< 0.001) revealed statistically Highly Significant with the t-values 2.85, 6.47, 7.70, and 10.91. Lajjalu having synonym Prarochani, corrects Aruchi, further corrects Agni dushti by pachana property of Tikta rasa in turn correcting the rasavaha srotodushti and production of Upadhatu Arthava qualitatively and quantitatively. Lajjalu also has the property of Rakta skandana due to sheeta veerya and it is also Yonirogahara.

In Duration of Bleeding, The effect of treatment before Treatment to During Treatment 1, the p value (<0.01) revealed statistically Highly Significant, Before Treatment to During Treatment2, Before Treatment to Follow Up 1 and Before Treatment to Follow Up 2, the p value (< 0.001) revealed statistically Highly Significant with t-values 3.68,5.66,6.88 and 9.89. Lajjalu contains alkaloids, thereby reduces the thickness of endometrium, resulting in reduction of duration of menstrual bleeding.

On Interval between Bleeding, The effect of treatment Before Treatment to During.

Treatment1, the p value (< 0.01) revealed statistically Highly Significant, Before Treatment to During Treatment2, Before Treatment to Follow Up1 and Before Treatment to Follow Up 2, the p value (< 0.001) revealed statistically Highly Significant with values 3.55, 5.47, 5.62, and 11.45. Lajjalu because of the garbhashaya shuddhi karma, and correcting the agni by deepana, pachana, agni vardhaka property there by correcting the rasa dushti and regularises the menstruation.

In Consistency of Bleeding, The effect of treatment Before Treatment to During Treatment 1, the p value (< 0.01) revealed statistically Highly Significant, Before Treatment to During

Treatment2, Before Treatment to Follow Up 1 and Before Treatment to Follow Up 2, the p value (< 0.001) revealed statistically Highly Significant with values 3.32, 3.89, 5.10, and 10.09. Lajjalu by deepana pachana guna helps in correcting rasa dhatu vaishamya inturn corrects tha artava vaishamya.

In lower abdomen pain, The effect of treatment before treatment to during treatment 1 p-value (>0.05) is non significant, before treatment to during treatment 2 the p-value (p<0.05) is statistically significant, before treatment to follow up1 and follow up2 p-value (p<0.001) is statistically highly significant with $\chi 2$ values 3.24, 5.7, 17.14 and 26.66. When the disease pathology was corrected by Lajjalu due to its Yonirogahara property, the associated symptom lower abdominal painl also reduced.

In Body Ache, The effect of treatment before treatment to during treatment 1 p-value (<0.05) is statistically significant, before treatment to during treatment 2, before treatment to follow up1 and before treatment to follow up 2 p-value (p<0.001) is statistically highly significant with $\chi 2$ values 4.44, 13.32, 21.52, and 32.72. When the disease pathology was corrected by Lajjalu due to its Yonirogahara property, the associated symptom lower abdominal painl also reduced.

In Low Backache, The effect of treatment before treatment to during treatment 1p-value (>0.05), is statistically non significant, before treatment to during treatment 2, before treatment to follow up1 and before treatment to follow up 2 the p-value (p<0.001) is statistically highly significant with $\chi 2$ values 3.24, 11.6, 17.14, and 21.52. As the main symptoms were treated, the associated complaints also reduced due to Yonirogahara property of Lajjalu.

In Giddiness, The effect of treatment before treatment to during treatment 1p-value(<0.05), is statistically significant, before treatment to during treatment 2, before treatment to follow up1 and before treatment to follow up2 p-value (p<0.001) is statistically highly significant with $\chi 2$ values3.94, 12.12, 19.78, and 19.78. Lajjalu having sheeta veerya is pitta shamaka.

In Weakness, The effect of treatment before treatment to during treatment 1, p value (>0.05) is statistically non significant, before treatment to during treatment 2 and before treatment to follow up1 p-value (<0.01) is statistically highly significant, and before treatment to follow up2 p-value (<0.001) is statistically highly significant with $\chi 2$ values 2.06,7.02, 7.02 and

28.98. Lajjalu is Yoni rogahara and is responsible for for Rakta skandana preventing further occurrence of Raktakshaya.

In Pallor, The effect of treatment before treatment to during treatment 1p-value (>0.05), is statistically non significant, before treatment to during treatment 2, before treatment to follow up1, before treatment to follow up 2 p-value (<0.01,<0.001and <0.001) is statistically highly significant with $\chi 2$ values 2.1, 10, 13.32 and 26.66. Lajjalu Ghana Vati corrects Pitta Dushti.

In Thirst, The effect of treatment before treatment to during treatment 1 p-value (>0.05), is statistically non significant, before treatment to during treatment 2 the p value <0.01 is significant, before treatment to follow up1 and before treatment to follow up2 p-value (<0.001) is highly significant with $\chi 2$ values 2.66, 8.1, 12.12 and 25.6.

The drug Lajjalu is having Sheeta Veerya. Hence, it is Pitta shamaka.

On Drowsiness, The effect of treatment before treatment to during treatment 1 p-value(< 0.05) is statistically significant, before treatment to during treatment 2, before treatment to follow up 1 and before treatment to follow up 2 with p-value (<0.01) is highly significant with $\chi 2$ values 5, 8.1, 8.1 and 10. Lajjalu is Kaphahara. The Anti-depressant,anti-oxidant and mood boosting properties of Lajjalu are helpful in this condition.

CONCLUSION

ASRIGDARA is a disorder which plagues many women at some time or other of their life time. The drug Lajjalu Ghana Vati contained the drug which are having properties like pachana, rakta stambhana, pitta and kapha shamana and srotho shodana. Hence, the drug has proven to be effective in the treatment of Asrigdara. Significant improvement is seen in all the criteria of assessment in treating Asrigdara. No adverse reactions and side effects were reported in the present study. So Lajjalu Ghana Vati is proved to be a highly effective, cost effective single drug therapy in the management of Asrigdara.

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