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Research Article

A CLINICAL STUDY TO EVALUATE THE EFFICACY OF *ASTHAPANA BASTI* AND *UTTAR BASTI* IN *ASRIGDARA* W.S.R TO ABNORMAL UTERINE BLEEDING

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ABSTRACT

Regular periods are necessary to maintain good health of women. Any abnormality in *Rituchakra* leads to excessive and irregular uterine bleeding which is known as *Asrigdara* which can be correlated to Abnormal Uterine bleeding. In Ayurvedic text, many preparations are described to treat *Asrigdara. Samshodhan* therapy is mainstay in the management of *Artava* related disorders of which *Basti* is supreme to manage *Asrigdara.* In conventional science, Hormonal therapy is given but chances of recurrence of the disease are high. This study was planned to provide simple, safe, non- hormonal drug for the patients of *Asrigdara*. Total 40 patients fulfilling the inclusion criteria were selected randomly from Dept. of Stree roga and Prasuti tantra O.P.D.and I.P.D. The total effect of drug was evaluated on the basis of signs and symptoms after completion of therapy. Overall effect of therapy shows in group-I 6 (60%) patients were markedly improved, 11 (61.11%) were partially improved and 1 (5.6%) was not improved and group II- 6 (33.33%) patients were cured, 9 (50%) were markedly improved, 2 (11.1%) were partially improved, and 1 (5.6%) was unimproved. Thus, *Basti Chikitsa* manifested promising results for the management of *Asrigdara,* although hormonal pill manifested better cycle but for shorter duration.

INTRODUCTION

A healthy woman lays the foundation of a healthy family and society. In today scenario, disorder of menstruation is the commonest among all the gynaecological complaints which have direct effect on the physical as well as psychological health of the female. In the past, women used to experience relatively less number of cycles due to more number of pregnancies and prolonged lactational amenorrhea. But in present era with changing role of women in society, there is occupational and community workloads thereby increase in psychological upsets which alters the length and frequency of menstrual periods.

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The victimized patients end up with general debility and anaemia. The length of *Rituchakra* (menstrual cycle) is usually 28-30 days. Any abnormality in *Rituchakra* leads to excessive and irregular uterine bleeding which is known as *Asrigdara* (Abnormal Uterine Bleeding). It is unambiguously explained in all the classics with detailed description of its *Nidana*, *Rupa*, *Chikitsa*, and *Sadhya-Asadhyata*. In Ayurvedic texts, *Asrigdara is* described in *Charak Samhita* as a separate disease in '*Yonivyapatachikitsaadhyaya*'[1] He also explained it as one of the *Raktapradoshajvikara* and also under *Pittavrutapanvayu. Acharya Sushruta* explained it as a separate disease entity and mentioned it under *Pittasamyuktaapanvayu* and *Raktapradoshajvyadhi*[2]. *Acharya Vagbhatt* (A.S.) explained *Raktayoni* and said *Asrigdara* and *Pradar* as its synonyms[3]. In modern science *Asrigdara* can be closely correlated to Abnormal Uterine Bleeding (AUB). In Ayurvedic text many preparations are described to treat *Asrigdara; Samshodhan* therapy is mainstay in the management of *Artava* related disorders. Among these, *Basti* treatment

is mentioned as supreme to manage *Asrigdara*[4]. A comparative clinical study was performed between *Kushadi Asthapana Basti*[5] followed by *Kashmarya Kutaj Uttar Basti*[6] with Ovral-L (Hormonal Preparation).

AIMS AND OBJECTIVES

1. To scrutinize the literature pertaining to disease *Asrigdara* in Ayurvedic classics and AUB in modern texts.
2. To provide simple, safe, Ayurvedic management for the patients of *Asrigdara*.
3. To evaluate therapeutic efficacy of *Asthapana Basti* and *Uttar Basti* in *Asrigdara*.
4. To find out the adverse effect of *Asthapana Basti, Uttar Basti* during this study

Ethical Clearance: Ethical clearance for conduction of the clinical trial involving human subjects was taken from the IEC before the commencement of trial.

Justification for Selection of Drug

Use of two or three *Asthapana Basti* followed by *Uttarbasti* is beneficial in disorders of female reproductive system.[7]

Clinical study

Table 1: Treatment protocol

Trail Groups	Drug	Dose	Route
Group-I	*Kushadhi Asthapana Basti*	1200ml once a day for two consecutive days on the third day *Uttar Basti* was given in dose of 4ml for three consecutive cycles after two days of clearance of menses	Per rectal
	Kashmarya Kutaj Uttar Basti		Trans-cervical
Group-II (standard group)	Tab Ovral-L (Levonorgestrel 0.15mg + Ethinylestradiol 0.03mg)	1 tab once a day for 21 days (from 5th day of menses for 3 consecutive cycles)	Oral

MATERIAL AND METHOD

Total 40 patients of *Asrigdara* and fulfilling the inclusion criteria were selected for this study, from Department of Stree Roga and Prasuti Tantra O.P.D of R.G.G.P.G. Ayurvedic Hospital Paprola the selected patients were randomly divided into two groups named as Group I and Group II.

Criteria for Selection of Patient

Inclusion Criteria

- Patients who were willing for the trial.
- Married patients between the age group 20-50 years.
- Patients diagnosed as AUB without organic pathology
- Patients, with either one of them or all, having following symptoms like prolonged, excessive bleeding or inter menstrual bleeding.

Exclusion Criteria

- Patients not willing to participate in the trial.
- Patients with uterine and pelvic pathology like fibroid>5cm, endometrial and endocervical polyp, adenomyosis, PID and Ca cervix etc. or any chronic systemic or metabolic disorder.
- Hb gm%<6gm%
- Patients having bleeding sites other than uterus.
- Patients having bleeding due to coagulation disorders.
- Women using IUCD

Follow up

Patients were followed up monthly for three consecutive cycles (during drug intervention) and monthly for three consecutive cycles (during drug free period) to assess the recurrence of AUB

Criteria of Assessment

The improvement in patients was assessed on the basis of relief in sign and symptoms of disease. For this purpose *Asrigdar*a was given scoring according to their frequency and intensity. The details of the score adopted in this study are as follows.

Grading of Assessment Criteria

The patients were advised to use standard size sanitary pads 21 x 7.5 x 0.5 cm made of cotton and scoring was done purely on the basis of patient's statement. The parameters of assessment criteria were graded as follows:

Symptoms of *Asrigdara*

Following scoring system was adopted to assess the effect of treatment.

Table 2: Subjective Parameters and Scoring

Parameter	Criteria	Grade
Intensity of Bleeding	1 – 2 completely soaked pad/ day	0
	3 – 4 completely soaked pad/ day	I
	5 - 6 completely soaked pad/ day	II
	>7 completely soaked pad/ day	III
Duration of Bleeding	3– 5 days	0
	6– 7 days	I
	8– 9 days	II
	>9 days	III
Amount of Flow	Moderate	0
	Scanty	I
	Heavy (without clots)	II
	Heavy (with clots)	III
Intermenstrual Period	28 – 35 days	0
	24 – 27 days	I
	20 – 23 days	II
	< 20 days or >35 days	III
Pain during Menstruation	No pain	0
	Mild pain, women complained of pain, but did not require any drug for relief.	I
	Moderate pain, women complaining of pain; took one or two doses of drug for relief pain did not affect routine work.	II
	Severe pain, women complained of pain, took 3- 4 doses of drug for relief. The pain influenced general activity.	III
Pallor	Hb>11 gm%	0
	Hb- 9-11 gm%	I
	Hb -7-<9 gm%	II
	Hb-<7 gm%	III

Table 3: Criteria for final assessment of results

Complete remission	Patients showing more than 90% relief in intensity, duration, Intermenstrual period, relief of pain and associated symptoms.
Cured	Patients showing 75%-89% relief in intensity, duration, Intermenstrual period, relief of pain and associated symptoms.
Markedly improved	Patients showing 50%-74% relief in above mentioned symptoms.
Partially improved	Patients showing 25% - 49% of relief in symptoms.
Unimproved	Patients showing less than 24% of relief in symptoms.

OBSERVATION AND RESULT

In the present study, 40 patients were registered and studied; these patients were treated into two groups randomly. Patients of Group 1 were given *Kushadi Asthapana Basti* and *Kashmarya Kutaj Uttar Basti* and while Standard Group II were given tab Ovral- L (Oral contraceptive pill). 20 patients in group 1 and 20 patients in Group II were registered but 2 patients in both the groups could not complete the trial and dropped out. Hence the clinical data is presented according to 18 cases.

Table 4: Effect of Therapy on assessment criteria during follow ups GP-I

Assessment criteria	BT Mean score	F_1 Mean score	% relief after F_1	F_2 Mean Score	% relief after F_2	F_3Mean score	% relief after F_3
Duration	2.222	1.722	22.50	0.778	64.99	0.333	85.01
Intensity	1.333	1.278	4.13	0.833	37.50	1.000	24.98
Interval	1.500	1.400	6.67	1.278	14.8	0.889	40.73
Amount	2.167	1.889	12.82	1.278	41.02	1.111	48.73
Pain	0.667	0.333	50.07	0.167	74.96	0.111	83.4

Table 5: Effect of Therapy on assessment criteria during follow ups GP II

Assessment criteria	BT Mean score	F_1 Mean score	% relief after F_1	F_2 Mean score	% relief after F_2	F_3 Mean score	% relief after F_3
Duration	2.278	1.000	56.10	0.222	90.255	0.056	97.54
Intensity	1.500	0.900	40.00	0.833	44.47	0.222	85.2
Interval	1.667	0.722	56.69	0.700	58.00	0.500	70.00
Amount	1.722	1.000	41.92	0.556	67.71	0.540	68.64
Pain	0.500	0.333	33.4	0.278	44.4	0.222	55.6

Table 6: Effect of therapy on associated symptoms in Gr I during follow ups

Associated symptoms	No. of patients						
	BT	F_1	%	F_2	%	F_3	%
Leg cramps	5	4	20	2	60	1	80%
Nausea	3	2	33.33	2	33.33	1	66.67%
Vomiting	2	2	00	1	50	1	50%
Generalized weakness	10	6	40	5	50	00	100%
Backache	5	4	20	3	40	1	80%

Table 7: Effect of therapy on associated symptoms in Gr II during follow ups

Associated symptoms	No. of patients						
	BT	F_1	%	F_2	%	F_3	%
Leg cramps	3	2	33.33	2	33.33	1	66.67%
Nausea	5	3	40	2	60	1	80%
Vomiting	2	2	50	1	50	1	50%
Generalized weakness	10	7	30	5	50	3	70%
Backache	4	3	25	2	50	1	75%

Table 8: Statistical analysis of effect of therapy in Group I

Parameter	Mean score		Relief difference	%	S.D ±	S.E ±	't'	P	Results
	B.T	A.T							
Duration	2.222	1.389	0.833	37.52	0.383	0.0904	9.220	<0.001	HS
Intensity	1.333	0.944	0.389	29.24	0.502	0.118	3.289	0.004	S
Interval	1.500	0.944	0.556	37.06	0.511	0.121	4.610	<0.001	HS
Amount	2.167	1.111	1.056	48.73	0.539	0.127	8.304	<0.001	HS
Pain	0.667	0.167	0.500	74.96	0514	0.121	4.123	<0.001	HS
Hb gm%	1.167	0.611	0.556	47.64	0.511	0.121	4.610	<0.001	HS

Table 9: Statistical analysis of effect of therapy on Group- II

Parameter	Mean grades		% relief difference	%	S.D ±	S.E ±	't'	P	Results
	BT	AT							
Duration	2.278	0.333	1.944	85.33	0.938	00.221	8.799	<0.001	HS
Intensity	1.500	0.333	1.167	77.8	0.383	0.0904	12.907	<0.001	HS
Interval	1.667	0.722	0.944	56.867	0.998	0.235	4.014	<0.001	HS
Amount	1.722	0.722	1.000	58.07	1.534	0.362	2.766	0.013	S
Pain	0.500	0.0556	0.444	88.8	0.511	0.121	3.688	0.002	S
Hb gm %	1.222	0.611	0.611	74.66	0.502	0.118	5.169	<0.001	HS

Table 10: Inter group comparison over criteria of assessment

Parameter	Percentage relief		Diff. in %	S.D ±	S.E ±	Unpaired 't' test	P	Result
	Gr. I	Gr. II						
Duration	37.5	85.366	47.87	0.7163	0.2388	4.6536	<0.001	HS
Intensity	29.167	77.778	48.61	0.4465	0.1488	5.226	<0.001	HS
Interval	37.037	40	2.963	0.4984	0.1661	0.6689	>0.05	NS
Amount	48.718	67.742	19.02	1.2538	0.4179	0.2659	>0.05	NS
Pain	75	88.889	13.89	0.5129	0.171	0.325	>0.05	NS
Hb g%	47.619	50	2.381	0.5065	0.1688	0.3291	>0.05	NS

Figure no. 1: Bar Diagram showing intergroup comparison over criteria of assessment

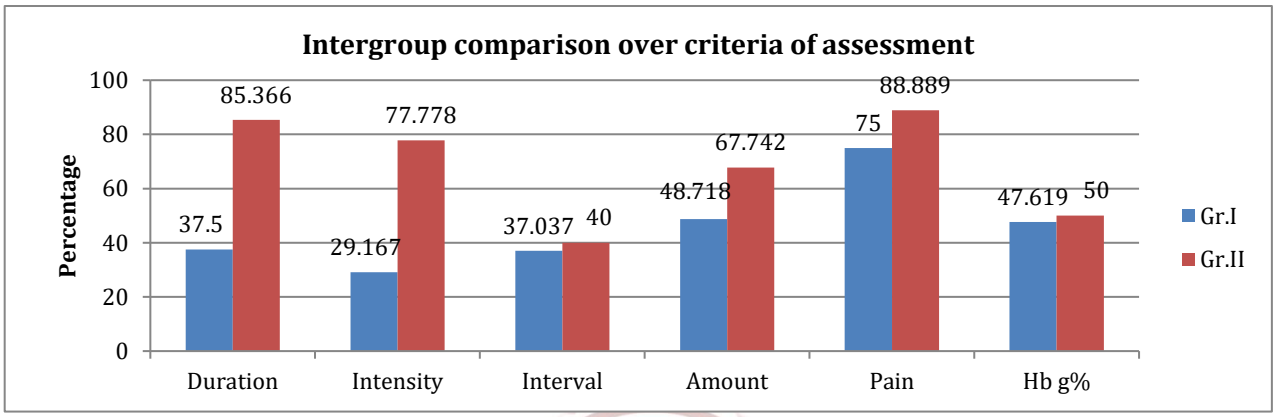


Table 11: Effect on associated symptoms in Group I, before and after treatment

Associated symptoms	No. of patients		Total relief	
	B.T	A.T	Difference	%
Leg cramps	5	2	3	60%
Nausea	3	1	2	66.67%
Vomiting	2	1	1	50%
Generalized weakness	10	7	3	30%
Backache	5	1	4	80%

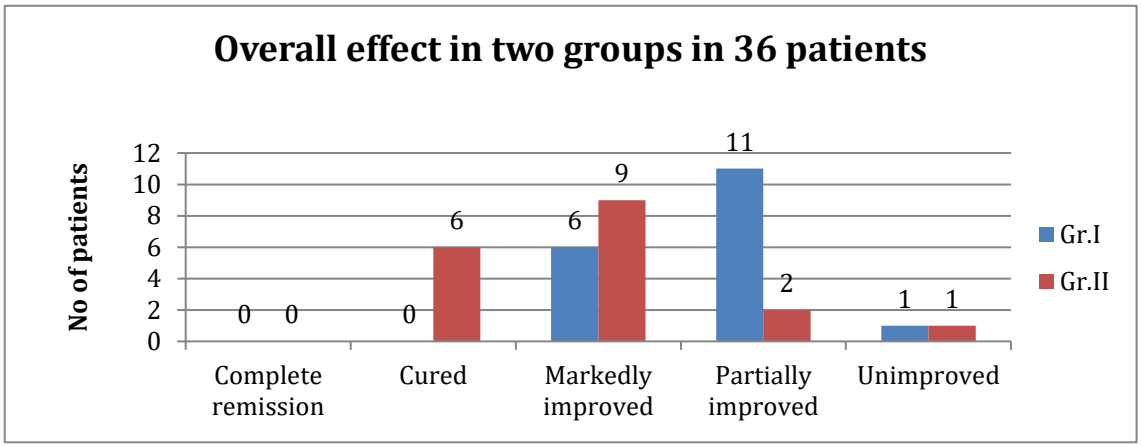
Table 12: Effect on associated symptoms in Group II, before and after treatment

Associated symptoms	No. of patients		Total relief	
	B.T.	A.T.	Difference	%
Leg cramps	3	1	2	66.67%
Nausea	5	2	3	60%
Vomiting	2	1	1	50%
Generalized weakness	10	4	6	60%
Backache	4	1	3	75%

Table 13: Overall effect in two groups in 36 patients

Assessment	Group I patients	Group I %	Group II patients	Group II %	Total	%
Complete remission	00	00	00	00	00	00%
Cured	00	00	06	33.33	06	16.67%
Markedly improved	06	60	09	50	15	41.67%
Partially improved	11	61.11	02	11.1	13	36.11%
Unimproved	01	5.6	01	5.6	02	5.6%

Figure 2: Bar Diagram showing Overall Effects in both groups



Overall Results

Group I- 6 (60%) patients were markedly improved, 2 (61.11%) patients were partially improved and 1 (5.6%) patient was not improved.

Group II- 6 (33.33%) patients were cured, 9 (50%) patients were markedly improved, 2 (11.1%) patients were partially improved, and 1 (5.6%) patient was unimproved.

Drugs Free Follow Up

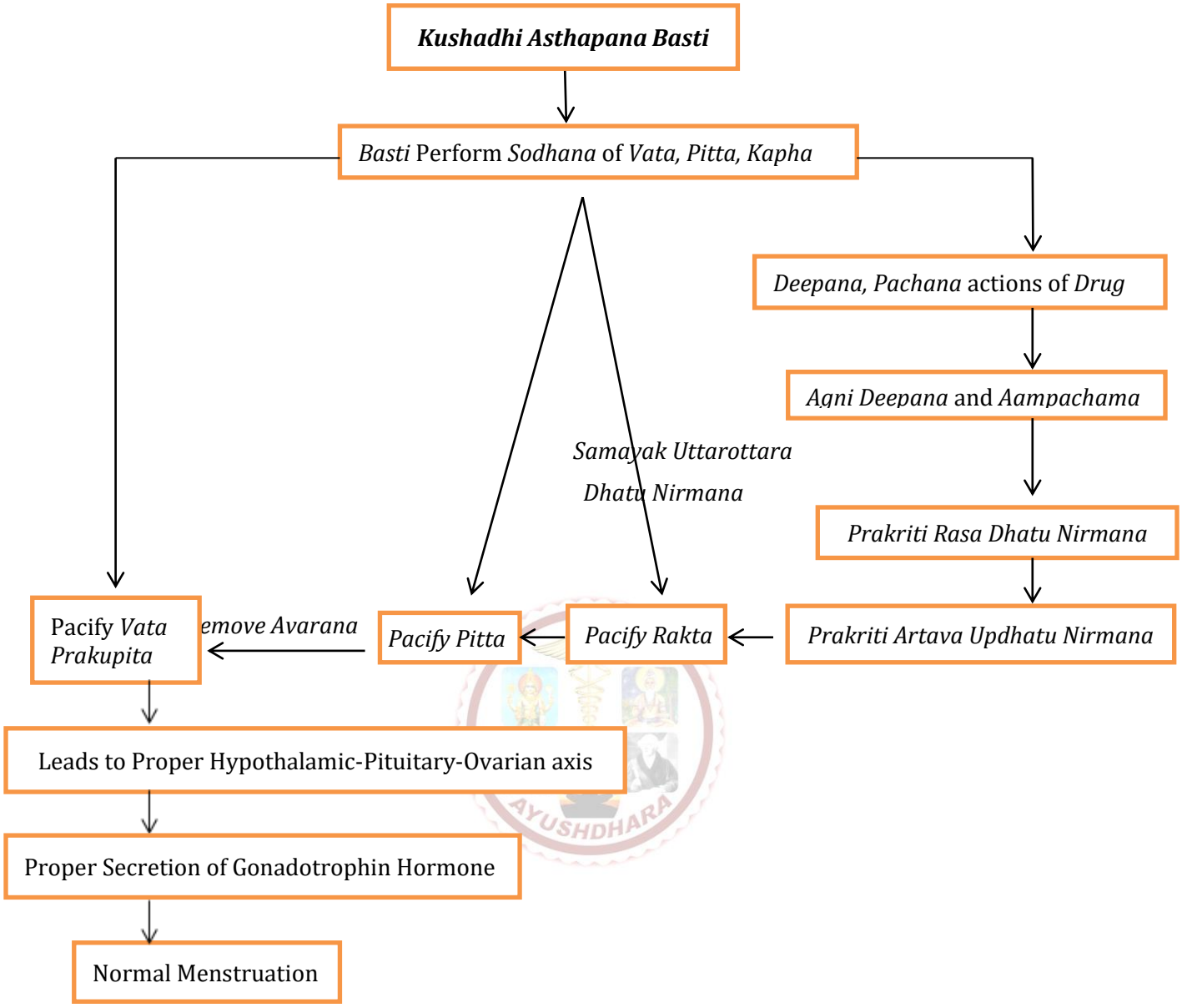
After three months of drug free follow up, it was observed that in Group I relief in assessment criteria and associated symptoms remained even after discontinuing the drug in majority of Patients. But in Group II the relief in assessment criteria and associated symptoms didn't remain after discontinuing the drug in majority of patients.

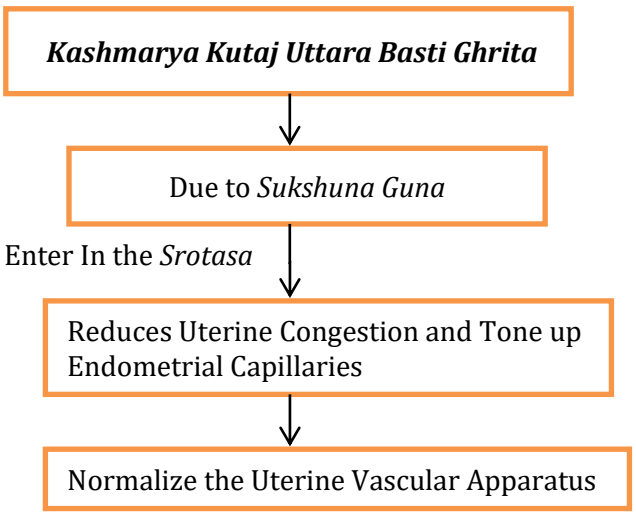
DISCUSSION

Probable Mode of Action of *Basti* Contents

- ***Saindhava*[8]:** *Agnideepana, Tridoshashamaka, Vrishya* properties which help in *Strotosodhana* and *Lekhana* and *Kapha shamaka* properties help in decrease the production of oestrogen leading to reduced hyperplasia of endometrium.
- ***Madhu*[9]**: *Having Sukshma guna,* it reaches up to micro channels thus, carries the drug at microcellular level.
- ***Madhu, Saindhava* and *Sneha*** help to form a homogeneous mixture of the *Basti dravya* and these help to deliver the drug through the micro channels at the cellular level and improve general condition of body, tone up endometrial capillaries and reproductive system.
- ***Kalka* and *kwath***: Mostly drugs have *Deepana, Pachana, Shothahara*, *Raktastambhaka, Rasayana, Vranaropana, Balya, Sandhaneeya karma*. These drugs reduce uterine congestion and decrease amount of uterine bleeding. Our *Shothahara* drugs are nothing but types of anti-inflammatory drugs. So, maintain the prostaglandin levels thus reducing menstrual blood loss and it also reduces uterine congestion**.**
- **Probable Mode of Action of *Kashmarya Kutaj Uttar Basti*:** *Uttarbasti* is the main line of treatment in *Yonivyapada*[10] as it strengthens the *Garbhasaya* by applying drug directly through *Uttarmarga. Kashmaryakutaj ghrita* having *Tridoshashamaka, Shothahara, Dahaprashamana, Vednashamaka, Deepana, Raktastambhan, Raktashodhaka* properites, balances the *Tridosha. Kashmaryakutaj* is lipid soluble drug thus it is passively diffused across the membrane gradient and breaks down the *Samprapati* of *Asrigdara.*
- *Basti*, in general regulates the Nervous Control and *Uttar Basti* regulates the ANS controlling pelvic organs. [11] There by gives proper feed back to the hypothalamus, by governing the H-P-O axis, it helps in the regulation of Follicular phase and Secretory phase maintenance and abolished the hormone imbalance which is the main etiological factor of AUB and regulates the vitiated *Dosha, Malas, and Apanavayu.*

The Schematic Diagram of *Samprapti Vighatan* of *Asrigdara* by *Kushadhi Asthapana Basti* and *Kashmarya Kutaj Uttar Basti*[12]





CONCLUSION

The *Basti* administered showed reduction in almost all symptoms and associated features of *Asrigdara.* The incidence of recurrence of symptoms was very less with *Basti* management while Hormonal therapy showed recurrence of symptoms and associated features after stoppage. Thus it can be concluded that *Basti Chikitsa has* promising results for the management of *Asrigdara,* although better cycle control can be achieved with hormonal pills but for shorter duration. *Basti chikitsa* is needed for prolonged duration to get better menstrual cycle control. Definitely recurrence of *Asrigdara* is lesser with *Basti* management as compared to Hormonal Pills.

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