



# A CLINICAL STUDY TO EVALUATE THE EFFICACY OF KUBERAKSHA VATI IN THE TREATMENT OF UDAVARTINI YONIVYAPADA (PRIMARY DYSMENORRHOEA)

Dr. Nisha Panhalkar<sup>1</sup>, Dr. Kavita Mule<sup>2</sup>

1 Assistant Professor -Department of Prasuti Tantra and Stree Rog, Hon, Shri. Annasaheb Dange Ayurved Medical College, Astha, Dist - Sangali, Maharashtra, India

2, Associate Professor - Department of Prasuti Tantra and Stree Rog, Yashwant Ayurveda College, Kodoli, Dist - Kolhapur, Maharashtra, India.

## ABSTRACT

Udavartini Yonivyapad is one of the Yonivyapad and is due to vikruta Vata. Vata get aggravated due to Vegadharana, other nidana factors and moves in reverse direction, then settles in Yoni and produces the pain, then discharges it with difficulty. The woman feels relief immediately after the discharge of menstrual blood. It is termed as Udavartini. Condition of udavartini may be compared with Dysmenorrohea. Dysmenorrhoea means painful menstruation. Majority of cases of dysmenorrhoea fall in to the group of primary dysmenorrhoea. The treatment of this disorder is still unsatisfactory in modern medicine, as the usage of anti spasmotic drugs, hormones may cause many side effects like hypertension, psychological disturbances etc. An attempt has been made to treat this condition with Ayurvedic system of medicine. So a research work has been carried out to study the efficacy of Kuberaksha vati oral administration . 70 patients with Udavartini yonivyapat diseases were selected randomly and the drug was administered for the period of 90days. Encouraging results were observed with the trial drug and the intensity of pain and the successive cycles were less painful. The orally administered drug Kuberaksha vati has Vedanasthapana, Vaatahara, Anulomana a properties. The present study Kuberaksha vati acts against Udavartini Yonivyapada and is highly effective.

Key words: Udavartini Yonivyapad, Dysmenorrhoea, Kuberaksha vati,

## INTRODUCTION –

The woman considered to be “Shakti”, the mother and source of creation in whose lap all of civilization is cradled. When we speak about “Women’s health” we understand that this encompasses many different issues during the different stages of her life. Every woman goes through a series of profound changes during her lifetime. The primary changes are called Menarche, Pregnancy, Postpartum and Menopause. Because of these drastic changes she risk for developing many Pathologies quality of woman’s life is dependent on many factors such as the culture and Position of society, environment, life style and changing demands of the society towards her. As the stree is a mula of reproduction, her health is prime important.

Menstruation is one of the physiological processes seen in the reproductive life of women. In Ayurveda, diseases related to the female reproductive system i.e. gynecological disorders are described under the caption of Yonivyapada mainly due to vitiation of Vata dosh<sup>1</sup>. Though initially all the classics have given the number of Yonivyapad as twenty. Udavarta Yonivyapad is one among the 20 Yonivyapadas and mainly Vata predominant.<sup>1</sup> According to Ayurveda, the Clinical entity characterized by pain, difficult expulsion of menstrual blood due to upward movement of rajas (Menstrual blood) propelled by vitiated vata. The upward movement is called Udavrittam<sup>1,2,3</sup>. Due to movement of flatus etc., natural urges in reverse direction, the aggravated vayu (Apana vayu) moving in reverse direction fills yoni (uterus). This yoni seized the pain, initially throws or pushes the rajas (menstrual blood) upwards, then discharges it with great difficulty. The lady feels relief immediately following discharge of menstrual blood. Since in this condition rajah (menstrual blood) moves upwards or in reverse direction, hence it is termed as Udavartini<sup>4</sup>. Besides painful and frothy menstruation, there are other pains of vata (body ache, general malaise etc.)<sup>5</sup>. In madhukosha commentary all around movement of vayu is said to be the cause of pain<sup>6</sup>. The discharge of frothy menstrual blood associated with kapha<sup>7</sup>. In modern science the udavartini disease can be interpreted as primary dysmenorrhea. On the basis of the symptom 'immediate relief of pain following discharge of menstrual blood' mentioned by Charaka, it appears to be the nearer to primary or spasmodic dysmenorrhea<sup>8-9</sup>. Dysmenorrhoea meaning "PAINFULL MENSTRUATION" is one of the major distressing factors in adolescent girls and women. It is one of most frequent of gynaecological complaints and it's incidence become higher with the degree of civilization of the community. Dysmenorrhoea effects 40-70% of reproductive age and effects daily activities in up to 10% of women<sup>10</sup>. Primary dysmenorrhoea usually onset is form the time of menarche with the onset of ovulatory cycles, with no abnormal finding on examination. This situation not only has a significant effect on quality of life and personal health but also has a global economic impact. According to our science the major cause of disease is prakupita vata with vilomgati and thus vata shaman with its prakruta gati / anuloma gati will solve the problem. This is an attempt to explore for safe and efficient ayurvedic treatment modalities for prakupita vata. Hence the study has been taken up to evaluate the role of Kuberaksha vati. The drug Kuberaksha vati in Bruhat Nighantu Ratnakara as Vedanasthapana, Vatahara, Anulomana properties is selected<sup>11</sup>

## AIM AND OBJECTIVES

1. To study the effect of Kuberaksha Vati in Udavartini Yonivyapad w.s.r to Primary Dysmenorrhea.
2. To Study Etiopathological and Clinical Features of Udavartini Yonivyapad.

## MATERIAL AND METHODS-

Total 70 clinically diagnosed and confirmed cases of Primary Dysmenorrhea of age group in between 16-25 were registered for the present clinical trial from O.P.D. / I.P.D. of P.G. Department of Prasuti-Stree Roga, after taking informed consent form with chief complain of Painful menstruation (primary dysmenorrhoea) with scanty or average amount of blood loss during menses along with associated symptoms such as Nausea, Vomiting, Giddiness, Irritability, Weakness for more than 2 cycles.

### Drugs

#### Kuberaksha Vati-

Kuberaksha Vati contains Latakaranja, Shunthi, Hingu, Souvarchal and Rasona for Bhavana. The quantity of these drugs are- Latakaranja 1 Karsha (12gm), Shunthi 1 Karsha (12gm), Hingu 1/2 Karsha (6gm), Souvarchal 1/2 Karsha (6gm) and Rasona rasa as bhavana dravya. according to reference. All the ingredients are measured and filter the powdered ingredients through the sieve and mixed homogenously. This mixture is now taken in khalva yantra and subjected bhavana with Rasona ras for a day

### Criteria for selection of patients:

#### A) Study Design-

A Randomized open clinical trial in patients diagnosed with Udavartini Yonivyapad was done.

#### B) Sample size -70 each group

C) Selection of patients - Female patients with complaints of Udavartini Yonivyapad were selected irrespective of age, religion, occupation and prakruti. From the Streerog and Prasutitantra O.P.D

**D) Selection criteria:-****I) Inclusion Criteria-**

1. Female patients of age group 16 to 25.
2. Patients with primary dysmenorrhoea i.e. pain without pelvic pathology.
3. Diagnosed patients of Udavarta yonivyapad according to symptoms.
4. Patient of any Caste, Parity, Income group and Occupation will be selected.

**II) Exclusion criteria-**

- 1) Patient of Secondary dysmenorrhoea, abnormal reproductive system.
- 2) Pelvic inflammatory disease or any serious systemic disorder likely to influence the menstrual cycle.
- 3) History of malignancy, hypo and hyper thyroidism, Diabetes mellitus, hypertension.
- 4) Women using IUD / Oral contraceptive pills.
- 5) PCOD and Other medical, surgical, Neurological conditions resulting dysmenorrhoea.
- 6) Endometriosis, DUB, Endometrial polyp. Etc.
- 7) Patients undergone Tubectomy.

**Criteria for withdrawal of patients -**

- 1) Patient unable to tolerate the medication.
- 2) Any adverse drug reaction.
- 3) Patient fail to report for follow up or irregular medication.
- 4) Patient not willing to continue further treatment.

**E) Informed Consent:**

The purpose of the study, nature of the study drug and the potential risks and benefits were explained to the patients in detail in non-technical terms. Thereafter their written consent was taken before starting the Medicine.

**METHOD:-****A) Plan of study-****Study Group:-**

140 diagnosed patients of Udavartini yonivyapad were randomly selected for the clinical study and were divided into two groups-

**Group A: -**

70 patients were treated with Kuberaaksha Vati & considered as Group A.

**Group B: -**

70 patients were treated with Shatpushpa churna & considered as Group B.

**PROCEDURE OF ADMINISTRATION-**

Patients were given the drug in following way-

**GROUP A- KUBERAKSHA VATI-**

Drug dosage	:250 mg 2 BID
Anupa	:Koshna Jala
Kala	:Morning and Evening before meal
Route	:Oral
Duration	:3 months

**GROUP B – SHATPUSHPA CHURNA**

Drug dosage : 3gm BID

Anupa :Koshna Jala

Kala :Morning and Evening before meal

Route :Oral

Duration :3 months

**Assessment Criteria-**

Clinical assessment was done on the basis of following criteria after completion of 3 consecutive menstrual cycles .The improvement in the patient was assessed mainly on the basis of subjective criteria. To assess the effect of therapy objectively, all the signs and symptoms were given scoring depending upon their severity.

**Subjective Criteria-****Gradations of Main Features:-1) Appling VAS Scale**

Observation	No(0)	Mild(1-3)	Moderate(4-6)	Severe(7-10)
Vedana	Absent (no pain)	Mild (dullachae,able to do routine work)	Moderate (severe pain,able to do work between two intermittennt pain.)	Severe (very severe pain,unable to do routine work)
Vedanakalavadhi	Absent	Mild (pain few hours prior &on the day of menses)	Moderate (pain 1 day prior & 1 <sup>st</sup> day of menses)	Severe (pain 2 days prior and 2 days of menses)
Artav praman	6-7pads/cycle	4-5pads/cycle	2-3pads/cycle	Spotting or 1 pad/cycle

**Gradations of Associated Features:-**

Associated Symptoms	No(0)	Mild(1)	Moderate(2)	Severe(3)
Nausea	Absent	1-2 times/day	3-5 times/day	More than 5times/day
Vomitting	Absent	1-2 times/day	3-5 times/day	More than 5 times/day
Giddiness	Absent	Occasionally	1-2 times/day	More than 2 times/day
Irritability	Absent	Aggressiveness with reason but calm immediately	Aggressiveness with reason but take time to calm	Aggressiveness without any reason
Diarrhoea	Absent	Occasionally	1-2 times/day	More than 2
Weakness	Absent	After heavy work, relieved soon and tolerate	After moderate work relieved later and tolerate.	After little work relievedlater but beyond tolerate.

**INVESTIGATIONS-**

Blood investigation-CBC

USG if needed

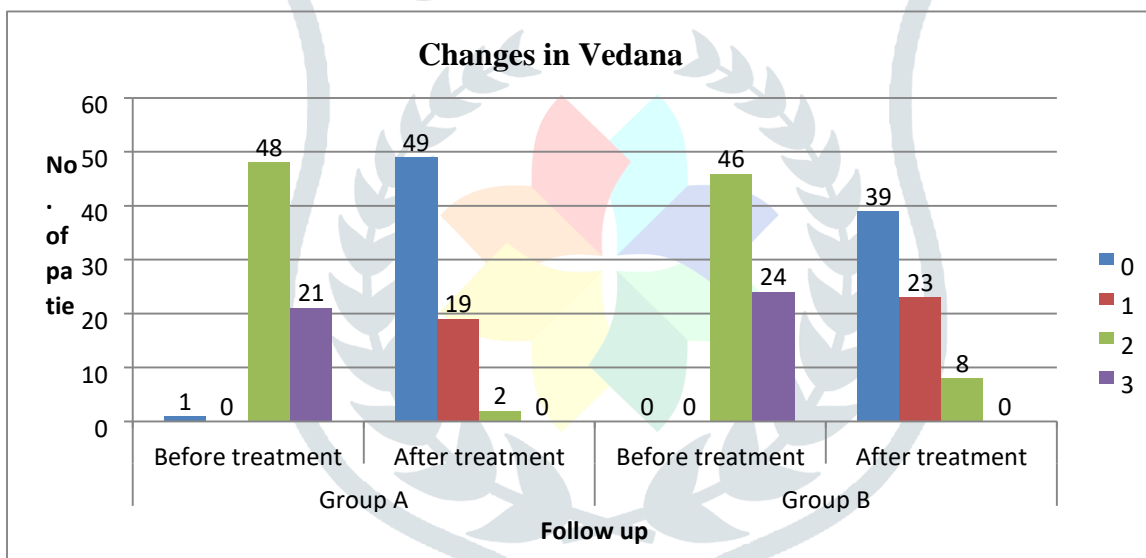
**FOLLOW UP: -**

5<sup>th</sup> day of each menses for 3 Consecutive cycles during treatment.

**OBSERVATION AND RESULTS**

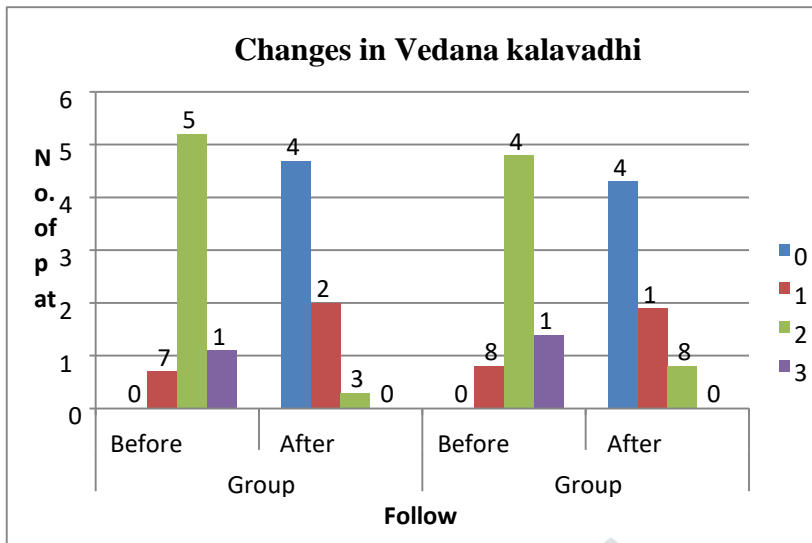
**1. Vedana**

Group	Mean score			Median diff.	IQR of diff. Q <sub>3</sub> - Q <sub>1</sub>	Sample size	Wilcoxon signed rank test (T+)	P Value
	B.T	A.T	Diff					
Group A	2.30	0.33	1.97	2.00	0.0 (2.0 - 2.0)	69	2415.00	< 0.001
Group B	2.34	0.56	1.79	2.00	0.0 (2.0 - 2.0)	70	2485.00	< 0.001



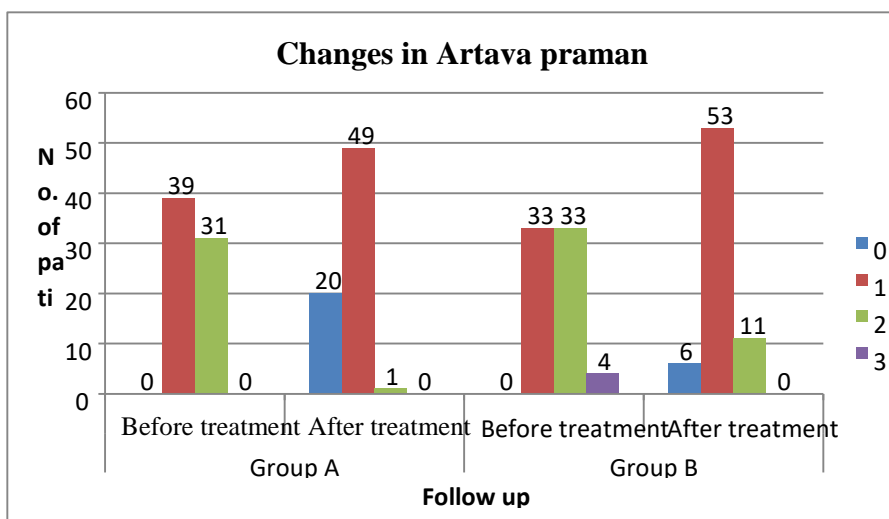
**2. Vedana kalavadhi**

Group	Mean score			Median diff.	IQR of diff. Q <sub>3</sub> - Q <sub>1</sub>	Sample size	Wilcoxon signed rank test (T+)	P Value
	B.T	A.T	Diff					
Group A	2.06	0.37	1.69	2.00	1.0 (2.0 - 1.0)	70	2485.00	< 0.001
Group B	2.09	0.50	1.59	2.00	1.0 (2.0 - 1.0)	70	2485.00	< 0.001



**3. Artava praman**

Group	Mean score			Median diff.	IQR of diff. Q <sub>3</sub> - Q <sub>1</sub>	Sample size	Wilcoxon signed rank test (T+)	P Value
	B.T	A.T	Diff					
Group A	1.44	0.73	0.71	1.00	1.0 (1.0 - 0.0)	70	1128.00	< 0.001
Group B	1.59	1.07	0.51	0.00	1.0 (1.0 - 0.0)	70	561.00	< 0.001



According to % Relief in Symptoms

**Table 1: % Relief in Symptoms of both group**

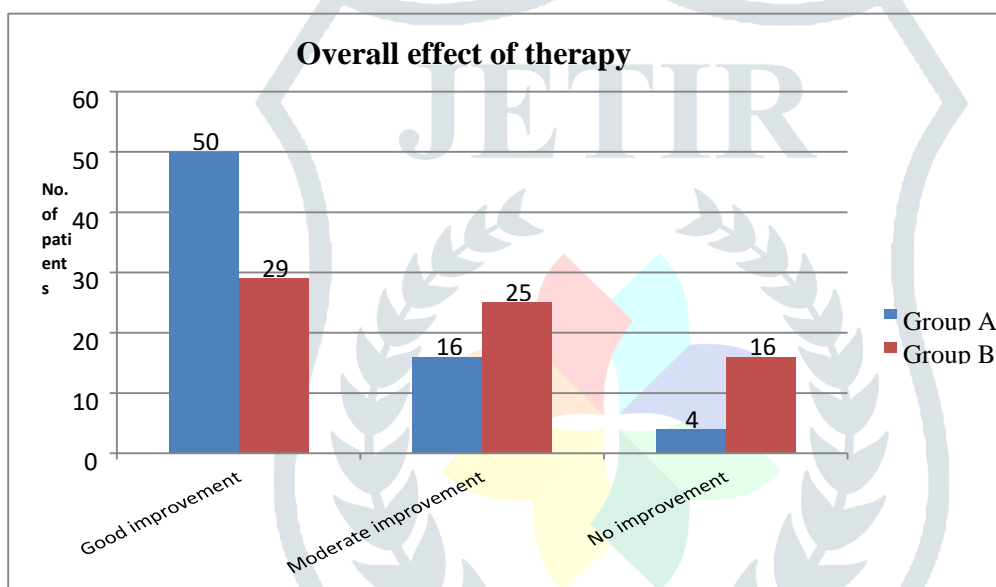
Parameter	Group A	Group B
Vedana	87.44%	79.29%
Vedana kalavadhi	83.81%	80.00%
Artava pramana	47.86%	28.33%
Nausea	94.83%	91.19%
Vomitting	82.22%	87.50%
Giddiness	74.82%	72.65%
Irritability	79.17%	42.08%
Diarrhoea	80.36%	55.69%
Weakness	77.05%	58.47%
<b>Mean % improvement</b>	<b>78.62%</b>	<b>66.13%</b>

**Distribution of patients according to relief:**

Total symptom score after treatment	Remark for overall Effect
0 – 3	Good improvement
4 – 6	Moderate improvement
7 and more	No improvement

**Distribution of patients according to relief:**

Overall Effect (patient wise)	No. of patients			
	Group A		Group B	
	Count	%	Count	%
Good improvement	50	71.43%	29	41.43%
Moderate improvement	16	22.86%	25	35.71%
No improvement	04	05.71%	16	22.86%
<b>Total</b>	<b>70</b>	<b>100.00%</b>	<b>70</b>	<b>100.00%</b>

**DISCUSSION**

According to Ayurveda, Aartava or Menstruation is a phenomenon, which is controlled and governed by Vata and specifically the Apana vayu, the sub type of the Vata dosha. Due to movement of natural urges in reverse direction, the aggravated Apanavayu moving in reverse direction fills the uterus. The uterus seized with pain, initially throws or pushes the raja (menstrual blood) upwards, then discharges it with spasmodic pain. The lady feels comfortable after discharging the menstrual blood. The main line of treatment is aimed at pacifying the aggravated Vata and correction of the direction of its normal flow.

Ayurveda drugs mainly having Vata Shamaka, Vata Anulomaka properties, Kuberaksha Vati has chosen for present clinical study because goal of any therapy should be to reduce symptoms, improving quality of life, prevent complication and side effects and above all which is easy to take with busy life schedule. The contents of Kuberaksha vati are Latakaranja, Shunti, Hingu, Rason, and Sauvarchal. This all drugs are kaph-vatashamak. They are having rochan, deepan, pachan, anulomak properties. Some of them are with ushna, tikshna, Sara guna. These together act to normalize vata dosha specially the apan vayu and once the apana vayu is regulated the functions of organs in apan kshetra are also normalize.

By applying Mann Whitney's U test, value of p being <0.05, it was concluded that Kuberaksha vati is significantly effective than Shatpushpa Churna to reduce Severity of pain, Duration of pain, fatigue (subjective criteria) in Udavartini Yonivyapada. Also, for other subjective parameters, p value is >0.05, therefore it can be concluded that there is no significant difference between efficacy of Kuberaksha vati and Shatpushpa Churna to reduce associated symptoms like Nausea, Vomiting, Headache. Statistical analysis after study it is shows that Kuberaksha vati is more effective in comparison to Shatpushpa Churna in Udavartini Yonivyapada (primary dysmenorrhoea).



## CONCLUSION

Therapeutic Effect of Group-A(Kuberaksha vati) Patients of this group showed relief by improvement in 87.44% in pain intensity, 83.81% in pain duration, 47.86% in menstrual flow amount, 94.83% in Nausea, 82.22% in Vomiting, 74.82% in Giddiness, 79.17% in Irritability, 80.36% in Diarrhoea , 77.05% in Weakness.

Therapeutic Effect of Group-B(Shatpushpa Churna)Patients of this group showed relief by improvement in 79.29% in pain intensity, 80.00% in pain duration, 28.33% in menstrual flow amount, 91.19% % in Nausea, 87.50% in Vomiting, 72.65% in Giddiness, 42.08% in Irritability, 55.69% in Diarrhoea , 58.47% in Weakness.

Percentage relief in symptoms in Group A was 78.62% and 66.13% in Group B. Comparing to this two-group concluded that trial group (Kuberaksha vati) was significantly better than control group (Shatpushpa Churna).

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