INTERNATIONAL AYURVEDIC MEDICAL JOURNAL



Research Article ISSN: 2320 5091 Impact Factor: 5.344

A CLINICAL STUDY ON EFFECT OF VIJAYADI VATI ON KASHTARTAVA w.s.r. TO PRIMARY DYSMENORRHEA

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ABSTRACT

Primary dysmenorrhoea or Painful menstruation is most commonly found gynaecological condition, and having a profound significance on most of the adolescent girls. Dysmenorrhoea itself is not a life-threatening disease but it is found to have a fervent impact on the daily activities and may result in missing work or school, inability to participate in sports or other activities. In Ayurveda Kashtartava- "kashten munchyati iti kastartava" i.e. the condition where Artava is shaded with great difficulty and pain is a condition that can be correlated with Primary dysmenorrhoea on the basis of cardinal symptom. Studies from India reported the prevalence range between 50 to 87.8%¹. Pain is significant in 5-20% who report severe dysmenorrhea or pain that prevents them from participating in their usual activities. Aims & Objective: To assess the efficacy of Vijayadi-Vati in the management of Primary Dysmenorrhea. Material and methods: Present study was carried out at OPD of Prasuti Tantra & Stri Roga National institute of Ayurveda, Jaipur. 18 patients were enrolled after fulfilling the selection criteria; however the study was completed on 15 patients as 3 patients were dropped out during the course of trial. Vijayadi-Vati (250mg) was the drug of choice for present clinical study, duration of trial was for 2 consecutive menstrual cycle and cases were followed after the course of trial drugs fortnightly for 2 consecutive menstrual cycles. Observations and Results: The final assessment was based on following parameters; Relief in intensity of pain, Relief (decrease) in duration of pain, Relief in associated symptoms, VAS Scale and Flow Amount. Out of them 04(26.66%) patients had excellent relief, 10(66.66%) patients showed significant relief and 01(06.66%) patient showed moderate relief. Conclusion: Vijayadi-Vati administered in cases of primary dysmenorrhea in above mentioned dose was found safe and effective in pain and associated symptoms of primary dysmenorrhea.

Keywords: *Kashtarvata*, Primary dysmenorrhea, Oral therapy.

INTRODUCTION

Ayurvedic View

As a disease *Kashtartava* is not mentioned anywhere in Ayurveda but it is considered and described as a symptom. According to *Acharya Charaka*², symptom

of a disease itself can constitute a disease. Keeping this panorama in mind and looking at high prevalence of the aliment, an attempt has been made to study the disease *Kashtartava* as a separate disease entity.

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The word *Kashtartava* can be expressed as – "*Kashthena muchyati iti kashtartava*" i.e. *Kashtena*— with great difficulty, so particularly the condition where *Artava* is shaded with great difficulty and pain is termed as "*Kashtartava*".³

For production of *Artava*, *Vyana* and *Apana* work in coordination with each other. Normal menstruation is among one of the function of *Apanavata*, so painful menstruation can be considered as *Apanavayudushti*. Contraction and relaxation of the uterus and its related organ is the function of *Vyana Vayu*, *Vyana Vata* has control over the muscles which bring about actions such as contraction, relaxation, extension, flexion etc. after which *Artava* is expelled out by *Anulomana Kriya* of *Apana Vayu*.

While going through the ancient Ayurveda text it may find out several disease entities, which come with Kashtartava as direct or indirect reference; Vatala Yonivyapad, Udavartini Yoni Vyapad, Suchimukhi Yonivyapad, Vataja Artavadushti & Artavakshaya.

And after reading the literature about these we can conclude that, disordered *Vata* is responsible for pain.⁴ More over *Acharya Charaka*⁵ has mentioned none of the gynaecological disease can be arise without affliction of aggravated *Vata*. In the process of *Samprapti of Kashtartava*, two main reasons for *Vata* discordance are:

- 1. *Margaavrodha* Obstruction either physiological or anatomical.
- 2. *Dhatukshaya* Low pain threshold or lack of the product concerned

Dhatukshaya:

Due to consumption of *Vata Prakopaka Ahara – Vihara*, the Vata gets aggravated leading to *Dhatu Kshaya* starting from *Rasa* and then *Rakta (Anuloma Kshaya)*. Since *Artava* is considered as *Upadhatu*²²*Artava* will be produced in less quantity than normal.

This will further vitiate *Vata Dosha* which further will produce *Kshobha in Garbhashaya*, the stage resembling to ischaemic condition of the uterus resulting in pain.

Margavarodha:

Acharya Sushruta has described it in Sharira Sthan⁶, and Dalhana commented that vitiated Doshas are Vata and Kapha individually and in combined form. The concept of Avarana also seems to play role producing pain, especially when the condition of Kaphavrita Vata is concerned. As in Kaphavrita Vyana pain as an additional symptom has been stated by Vangasena

Prakopa can occur in two ways

- 1. Svadhatu Vaishamya
- 2. Unmargagaman

Table 1: Samprapti

Dosha	Vata Pradhana Tridosha			
	• Vata -Vyana, Apana			
	Pitta -Ranjaka, Pachaka			
	Kapha -Present as Anubandhita Dosa			
Dushya	Dhatu - Rasa, Rakta, Artava			
	• Upadhatu – Artava			
Agni	Jatharagni, Rasagni, Raktagni			
Srotasa	Rasa, Rakta and Artavavaha Srotasa			
Srotodushti	Sanga and Vimargagamana			
Udbhavasthana	Amapakvashaya			
Roga marga:	Abyantara			
Sthana Samshraya	Garbhashaya			
Vyakti Sthana	Garbhashaya			

Modern View: Menstruation is a normal cyclic physiological manifestation of women's life. Accompanied with pain, it is called as dysmenorrhoea and a more realistic and practical definition includes cases of painful menstruation of sufficient magnitude so as to incapacitate day to-day activity⁷ in absence of pelvic pathology is called primary dysmenorrhoea.

Although aetiology of primary dysmenorrhea is still obscure, but according to the most accepted theory, the cause of pain is excessive or imbalanced number of prostaglandins secreted from the endometrium. This results in increased uterine contraction with a dysrhythmic pattern, increased basal tone and increased active pressure. Uterine hyper contractility, decreased uterine blood flow and increased peripheral nerve hypersensitivity contribute to pain. There are some reports that indicate the levels of prostaglandin $F2\alpha$ measured in menstrual fluid from tampons and found to be twice higher in the dysmenorrheic as against the non dysmenorrheic women.

Need of study

Some of previous research works which are done to treat primary dysmenorrhoea were either in the form of *Basti* or *Uttarabasti* but as we discussed earlier that this is not a life-threatening problem for which a patient will approach for different time consuming *Pancharkana* therapies. So, it is the need of the hour to find out an oral treatment option which is palatable, cost effective and can be taken easily with busy life schedule and will impart a permanent cure without side effects.

In Ayurveda classics, there are a lot of single and compound drugs available which are mentioned in several contexts. Most of them are not re-tested according to the current research methodology. Unless the drug is tested through recent methodology the drug will not get proper recognition in the scientific world. Kashtartava is a Vyadhi with Vata predominance. In this particular ailment, there is derangement of Apana and Vyana vayu. So, the treatment chosen should have enough potential perform Vatashamaka & Vatanulomana Karma. Keeping this fact in mind during present research work our trial drugs was- Vijayadi-Vati.

Material and Methods

Total 18 clinically diagnosed and confirmed cases of Primary Dysmenorrhea of age group in between 16-30 were registered for the present clinical trial from O.P.D. / I.P.D. of P.G. Department of *Prasuti-Stree Roga*, National Institute of Ayurveda (N.I.A.) after taking informed consent form with chief complain of *Kashtartvata* (primary dysmenorrhoea) with scanty or average amount of blood loss during menses along with associated symptoms such as Fatigue, headache, breast tenderness, fever, vertigo, pain in thigh and backache for more than 2 cycles.

Criteria for selection of patients:

Inclusion Criteria:

- Subjects coming with chief complaint of Kashatartava with scanty or average amount of menses
- 2. Subjects having scanty or average Amount of menses along with associated symptoms.
- 3. Subjects in age group of 16 to 30 years.
- 4. Subjects with H/O using analgesics and other drugs during menses.
- 5. Subjects suffering from *Kashtartava* for more than 2 consecutive cycles.

Exclusion Criteria:

- 1. Subjects below 16 & above 30 years of age.
- Subjects suffering from secondary dysmenorrhea; having organic pathology of uterus and adnexa.
 e.g. Fibroid uterus, carcinoma of endometrium, venereal diseases, PID etc.
- 3. HIV, VDRL, HBsAg positive subjects.
- 4. Subjects suffering from Systemic diseases.
- 5. Subjects using intra uterine contraceptive devices.
- 6. Subjects having pain abdomen associated with excessive bleeding p/v.
- 7. Subjects with H/O Thyroid dysfunction.

Criteria for withdrawal:

- 1. During the course of trial if any serious condition or any serious adverse effects occurs and that requires urgent treatment.
- 2. Subject herself wants to withdraw from the clinical trial.
- 3. Irregular follow-up.

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 procedure.

However, the study was completed on 15 patients as 3 patients were dropped out during the course of trial. All the 15 patients were given *Vijayadi-Vati* (250mg) twice a day with lukewarm water before taking meal

for two consecutive menstrual cycles.

Clinical assessment was done on the basis of following criteria after completion of 2 consecutive menstrual cycles and Cases were followed after the course of trial drugs fortnightly for 2 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.

Assessment of Pain (Dysmenorrhoea): A special scoring pattern was applied in symptoms:

Table 2:

PAIN INTENSITY:	Grade	
Absent	0	
Mild (pain do not interfere with daily activity)	1	
Moderate (daily activity hampers, relieves with analgesics)	2	
Severe (do not relieved by analgesics)	3	

Table no.3

DURATION OF PAIN	Grade
Absent	0
Pain for few hours	1
Pain for one whole day	2
Pain for>or=2 days	3

Table 4

NATURE OF PAIN	Grade
Absent	0
Occasional (Mild)	1
Dull (Continuous)	2
Spasmodic(Cramp like)	3

Table 5

MENSTRUAL FLOW AMOUNT (total no. of pads used during a cycle)	Grade
Scanty (<9 pads/cycle)	0
Average (9-12 pads/cycle)	1
Normal (13-15 pads/cycle)	2
Excessive (>15 pads/cycle)	3

Visual Analog Scale—



WORST PAIN

IMAGINABLE

Further it is assessed as follows —

Table 6:

0	No pain	Grade 0
1 - 3	Mild pain	Grade 1
4 - 6	Moderate pain	Grade 2
7 - 10	Severe pain	Grade 3

Associated Complaints — Total 11 complaints

Table 7:

0	grade 0
1 - 4	grade 1
5 - 8	grade 2
9-11	grade 3

Statistical Evaluation of results:

On the basis of observation various parameters were subjected to statistical analysis in terms of Mean, Standard Deviation and Standard error (SE). **Graph** in Stat Pad 3.1 software (Trial version), Wilcoxon matched-pairs signed ranks test was used for non-parametric data and results calculated. Paired t test was carried out.

Table 8: Shows the pattern of clinical recovery in various 'Subjective Parameters' of *Kashtartava* in 15 patients treated *with* "Vijayadi-Vati" orally – by Wilcoxon matched-pairs signed-ranks test.

S. No.	Symptoms	Mean		Diff.	% of	Relief	SD	SE	P value	Results
		BT	AT							
1.	Pain Intensity	2.400	3.400	2.00	83.33%		0.654	0.1690	< 0.0001	E.S.
2.	Pain Duration	2.333	0.4000	1.933	82.85%		0.798	0.2063	< 0.0001	E.S.
3.	Nature of Pain	2.533	0.7333	1.800	71.06%		0.6761	0.1746	< 0.0001	E.S.
4.	Flow Amount	1.467	1.533	0.06667	4.54%		0.5936	0.1533	> 0.05	N.S.
5.	Associated Symptoms	2.067	0.5333	1.533	74.16%		0.6399	0.1652	< 0.0001	E.S.
6.	VAS Scale	2.600	0.6000	2.00	76.92%		0.9258	0.2390	< 0.0001	E.S.

Extremely significant results are shown on Pain Intensity, Pain Duration, Nature of Pain, Associated symptoms and VAS Scale. Results on Flow amount were not significant.

Table 9: Shows the pattern of clinical recovery in various 'Associated Symptoms' of Kashtartava in 15 patients treated with "Vijayadi-Vati" orally -by Wilcoxon matched-pairs signed-ranks test.

S. No.	Symptoms	Mean		Dif.	% of Relief	SD	SE	P value	Results
		BT	AT						
1.	Nausea	0.800	0.1333	0.6667	83.33%	0.4880	0.1260	< 0.01	V.S.
2.	Vomiting	0.4000	0.1333	0.2667	66.67%	0.4577	0.1182	> 0.05	N.S.
3.	Fatigue	0.8667	0.1333	0.7333	84.60%	0.4577	0.1182	< 0.001	E.S.
4.	Headache	0.6000	0.2000	0.4000	66.66%	0.5071	0.1309	< 0.05	S.
5.	Fainting	0.2667	0.1333	0.1333	49.98%	0.3519	0.09085	> 0.05	N.S.
6.	Sweat	0.5333	0.1333	0.4000	75.00%	0.5071	0.1309	< 0.05	S.
7.	Diarrhoea	0.2000	0.06667	0.1333	66.65%	0.3519	0.09085	> 0.05	N.S.

8.	Constipation	0.80000	0.3333	0.4667	58.33%	0.5164	0.1333	< 0.05	S.
9.	Vaginal Discharge	0.1333	0.06667	0.0667	50.01%	0.2582	0.06667	> 0.05	N.S.
10.	Breast Tenderness	0.8000	0.2000	0.6000	75.00%	0.5071	0.1309	< 0.01	V.S.
11.	Giddiness	0.8000	0.1333	0.6667	83.33%	0.4880	0.1260	< 0.01	V.S.

Extremely significant results are shown on Fatigue, while Very significant results are shown on Nausea, Breast tenderness and Giddiness. Significant results

obtained on Sweat, Headache and Constipation. Results on Fainting, Vaginal discharge, Vomiting and Diarrhoea were Non-significant.

Table 10: Shows the % improvement of symptoms in both groups:

S.NO.	CARDINAL SYMPTOMS	RESULT IN PERCENTAGE
1.	Pain Intensity	83.33%
2.	Pain Duration	82.85%
3.	Nature of Pain	71.06%
4.	Flow Amount	04.54%
5.	Associated Symptoms	74.16%
6.	VAS Scale	76.92%
7.	Nausea	83.33%
8.	Vomiting	66.67%
9.	Fatigue	84.60%
10.	Headache	66.66%
11.	Fainting	49.98%
12.	Sweat	75.00%
13.	Diarrhoea	66.65%
14.	Constipation	58.33%
15.	Vaginal Discharge	50.01%
16.	Breast Tenderness	75.00%
17.	Giddiness	83.33%

It was found that Average percentage of relief was 67.8%,

Table 11: Overall Effect of Therapy

S. No.	Effect of therapy	Result	Group A	
			No.	%
1.	Mild	$(1 \text{ to } \le 25\%)$	00	0.00%
2.	Moderate	(>25 to ≤ 50%)	01	06.66%
3.	Significant	$(>50 \text{ to} \le 75\%)$	10	66.66%
4.	Excellent	(>75%)	04	26.66%

It was found that 04(26.66%) patients having excellent relief, 10(66.66%) patients showed significant relief and 01(06.66%) patient showed moderate relief.

DISCUSSION

As Painful menstruation is the dominant feature in both Primary dysmenorrhea and *Kashtartava*, Primary dysmenorrhoea maybe equated with *Kashtartava* in *Ayurveda* on the basis of symptomatology. Primary

dysmenorrhoea is one of the commonest gynaecological disorders, which, though not fatal, yet very disturbing for the young women, who suffer a lot due to this at the crucial period of their life. Many ladies suffer from severe mood swings, which has a duration half of their menstrual cycle. Females also suffer from anorexia & gastrointestinal upsets. Hence, primary dysmenorrhoea is really a very troublesome condition for a lady. The detrimental impact of dysmenorrhoea on the lives of women is under-appreciated. In many countries, dysmenorrhoea is the leading cause of recurrent short-term school and work absenteeism in adolescent girls and women¹⁰ and it has a negative impact on social, academic and sports activities in female adolescents¹¹.

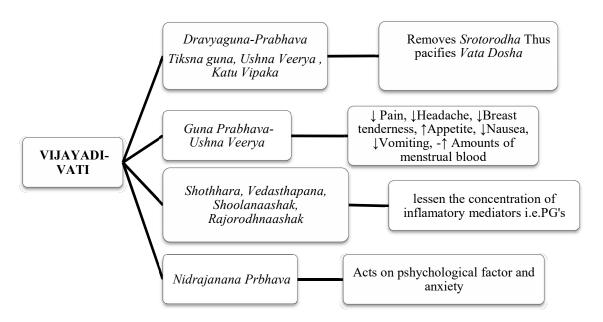
Ayurveda drugs mainly having *Vata Shamaka & Vata Anulomaka* properties; *Vijayadi Vati* has chosen for present clinical study because goal of any therapy should be to reduce symptoms, improving quality of life, prevent complication and side effects and above all which is easy to take with busy life schedule.

Probable mode of action of Vijayadi Vati:

So, the basic principle of Kashtartava Chiktsa revolves around pacifying vitiated Vata Dosha. Vijayadi-Vati has a direct reference in Bhaishajya Ratnavali for Kashtartava¹² (Primary Dysmenorrhoea). It has Tikta Rasa, Laghu, Tikshna Guna, Katu Vipaka and Ushna Virya. Thus, it removes the Srotoavarodha and thus pacifies Vata vitiation.

Analysis of various contents of *Vijayadi-Vati* reveals that: *Shothhara, Vedasthapana, Shoolanaashak* activity was present in all the drugs. While *Rajorodhnaashak* property was found in *Kumari-Sara* and *Nidrajanana* property was present in *Vijaya*.

Most of the drugs were having *Katu Vipaka* and *Ushna Veerya* having property of *Srotoshodhana*. Thus, by removing *Margavarodha* it pacifies vitiated *Vata* and as a result of this cardinal symptom of pain is relieved.



CONCLUSION

After completion of whole research work it can be concluded that *Kashtartava* is a border term, it can be compared with all the types of dysmenorrhoea, but when it is due to only *Vata*, it takes the appearance as primary dysmenorrhoea. *Kashtartava*, though not mentioned in classics, it is described on various places either as specific symptom of a disease, *Vatala Yonivyapada*, *Udavarta Yonivyapada*, *Vataja Arta-*

vadushti or as whole clinical picture of a disease i.e. Artavakshaya. As per pathogenesis, treatment for Kashtartava should be Vatashamana & Vatanulomana. Vatashaman chikitsa in form of Vijayadi-Vati is highly effective in disintegration of the pathogenesis of the disease. Average percentage of relief was 67.78%. The medicine given to patient has shown significant result without any side effects. The more studies should be conducted related to this.

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Source of Support: Nil Conflict Of Interest: None Declared

How to cite this URL: Upasana Sharma & Sushila Sharma: A Clinical Study On Effect Of Vijayadi Vati On Kashtartava W.S.R. To Primary Dysmenorrhea. International Ayurvedic Medical Journal {online} 2019 {cited August, 2019} Available from:

http://www.iamj.in/posts/images/upload/1219_1226.pdf