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Research Article

A RANDOMIZED CONTROLLED CLINICAL TRIAL OF *VIJAYADI-VATI* ON *KASHTARTAVA* (PRIMARY DYSMENORRHOEA)

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ABSTRACT

Nowadays Primary dysmenorrhea has become one of the commonest complaints in adolescent girls. Dysmenorrhea is a term which is being used for the condition where women may suffer from pain during menstruation. Studies from India reported the prevalence range from 50 to 87.8%. **Aims**: It was hypothesized that Ayurveda formulations- *Vijayadi-vati* and *Ashwagandha choorna* possesses properties like; *Vata-kapha shamak* (pacifies *Vata* and *Kapha*), *Shothahara* (anti- inflammatory), and *Balya* (potent rejuvenator and antioxidant) can be given as oral therapy in primary dysmenorrhoea. **Setting and Design:** This clinical study was an open randomized controlled study, based on a total of 30 clinically diagnosed patients, with *Kashtartava* (primary dysmenorrhoea) in the age group of 16-30 years from OPD/IPD of Prasuti & Stree Roga Dept. of National Institute of Ayurveda, Jaipur along with consideration of inclusion and exclusion criteria. **Methods and Material**: There were two groups in this trial, in **Group A:** Patients were treated with *Vijayadi Vati* and in **Group B:** with *Ashwagandha Choorna* orally before meals for two consecutive menstrual cycles. The treatment was started seven days before the due date to keep the uniformity. Follow-up was done after the completion of the course of trial drugs fortnightly for 2 consecutive menstrual cycles. This study was approved by the Institutional Ethical Committee with no. F10(5)/EC/ 2014/7228. **Statistical Analysis:** Mann-Whitney Test was used for comparison in the effect of trial drug between subjective parameters of two groups. **Results and Conclusion:** Significant improvement was seen in symptoms in both groups, comparing the symptomatic improvement in both groups it was found that the average percentage of relief was higher in 'Group A' i.e., 67.78%, followed by 'Group B' i.e., 60.44%. The result was encouraging with marked relief and no any adverse drug reaction was recorded in any group during and in the follow-up period in the present clinical study.

INTRODUCTION

Dysmenorrhea refers to painful menstruation of sufficient magnitude to incapacitate females from performing day-to-day activities[1]. This particular disease is of two types; primary and secondary, Primary dysmenorrhea is one of the commonest gynaecological disorders when there is the presence of pain during menstruation without any identifiable pelvic pathology. It is a much underrated disease and not addressed properly because of a preconceived mindset that there is certain negligence toward painful menstruation. Worldwide prevalence of Primary dysmenorrhoea ranges from 45-95% during reproductive age group[2]. A systematic review of studies from developing countries revealed that about 25%–50% of adult women and about 75% of adolescents experience pain during menstruation, with 5%–20% reporting severe dysmenorrhea or pain that is brutal enough to put a stop on carrying out their day-to-day activities.[3] It is though not fatal, that the detrimental impact of dysmenorrhea on the quality of life in females is under-appreciated. Across the globe,

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dysmenorrhea is a marshalling cause of recurrent short-term school and work absenteeism in adolescent girls and women[4] and it hurts social, academic and sports activities in female adolescents.[5]

All *Acharyas* have considered that for pain manifestation *Vata* vitiation is the main causative factor and *Vayu* has also been given prime importance in all gynaecological disorders.[6]

On reviewing Ayurveda classics, we found, that *Kashtartava* as a disease is not described anywhere in Ayurveda text books; *Brihatrayi & Laghutrayi* instated of that it is described as a symptom in many diseases. Acharya Charak has vouched for the fact that not all diseases need to be written by name in the classics a wise physician should understand diseases according to the involvement of *Doshas*, *Dushya*, etc.[7]

In Ayurveda classics, various gynaecological disorders; *Vatala, Udavarta* and *Suchimukhi Yonivyapad, Vataja Artavadushti*, and *Artavakshaya* show pain associated with menstruation along with backache, pain in groins & stiffness etc as a cardinal symptom. Besides this, there is no other abnormality of menstruation other than less amount or duration. Painful menstruation is the cardinal feature in both Primary dysmenorrhea and *Kashtartava*, the former can be equated with *Kashtartava* in Ayurveda based on symptomatology.

Samprapti

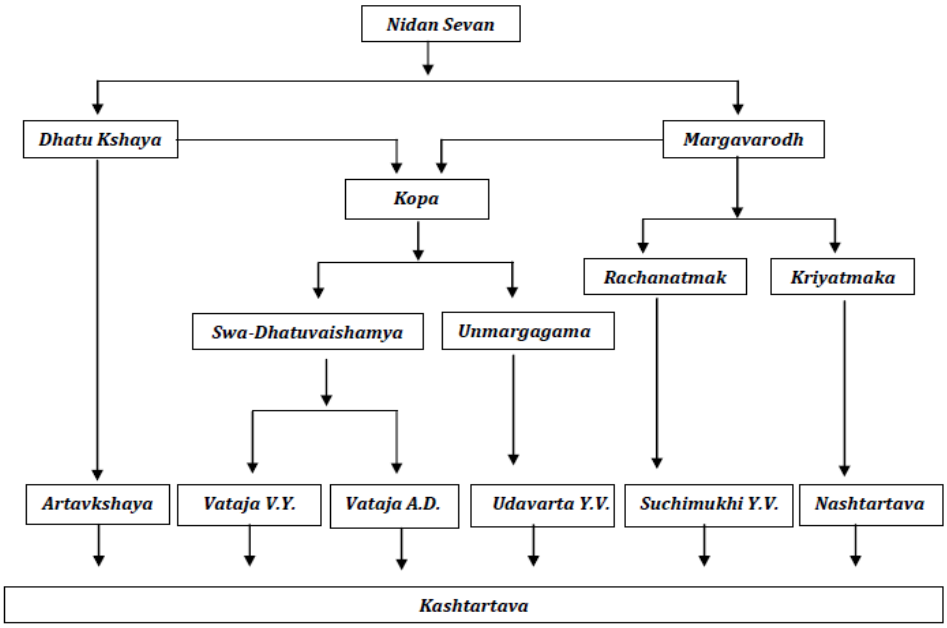
Etiopathogenesis of Primary dysmenorrhea

Current research studies suggest that primary dysmenorrhoea is a result of increased secretion of prostaglandins in endometrium during menstruation phase. These prostaglandins increase myometrial contractions and vasoconstriction that will lead to uterine ischemia and production of anaerobic metabolites. This ultimately results in the hypersensitisation of pain fibers, and lastly pelvic pain.[8]

According to Ayurveda in menstrual cycle bleeding phase is mainly dominated by *Vayu,* as the excretion of *Rajah* (menstrual blood) is one of the actions of *Apana vata*.[9]

Due to consumption of *Vata prakopaka ahara – vihara*, (diet and lifestyle that aggravates *Vata dosha*) *Vata* gets aggravated.

In the process of pathogenesis of primary dysmenorrhea, changes occurred in *Vata dosha* can be considered as foremost step. Vitiation of *Vata* can be occurred in two ways *Dhatukshaya* (state of malnutrition at micro cellular level) and *Margavarodha* (obstruction of passage for menstrual blood) (Figure 01) *Vata* is the main responsible factor, though other *Doshas* only be present as associates to it. So, pain is produced due to vitiation of only *Vata dosha* or in combination with other *Doshas*.



(Figure 01)

Dysmenorrhoea itself is not that fatal and grievous and needs emergency intervention but it is found to have a profound impact on quality of life so this is the need of the moment to find a palatable, easy-to-have, coast effective drug to treat primary dysmenorrhoea. Two Ayurveda formulations; *Vijayadi-vati & Ashwagandha choorna* were selected as trial drugs as both have *Ushna, Tikshna, Guna, Shothhar* (anti-inflammatory), *Vedanasthapan* (analgesic), *Yonishoolahar* (relieves vaginal pain), *Garbhashaya-shoolahar* (mitigates uterine pain), *Rajorodhanaashak* (alleviate obstruction of menstrual blood passage),

Vatanuloman (due regulation of *Vata*), *Vatashamak* (pacification of *Vata*) properties.

AIMS AND OBJECTIVE

1. To study the etiopathogenesis of *Kashtartava* with special reference to primary dysmenorrhea and to explore the clinical consequences.
2. To assess the efficacy of *Vijayadi-vati* in the management of *Kashtartava.*
3. To assess the efficacy of *Ashwagandha Choorna* in the management of *Kashtartava.*
4. To compare the efficacy of *Vijayadi-Vati* and *Ashwagandha choorna* in the management of *Kashtartava.*

Type of Research – Clinical

Design of Study - Randomized

Trial Methodology – Open trial

MATERIAL AND METHODS

Selection of Cases

36 clinically diagnosed and confirmed cases of primary dysmenorrhea in the age group 16-30 were registered for this particular clinical trial. Those were randomly divided into two groups. Out of 36 total, 30 patients completed the course of treatment. Those cases were selected from the O.P.D/I.P.D of Postgraduate Department of Prasuti Tantra & Stree Roga, National Institute of Ayurveda (N.I.A.) Hospital, Jaipur. The clinical trial was started only after taking the informed consent form.

Criteria for Selection of Patients

Inclusion Criteria

1. Subjects came with the chief complaint of painful menstruation with a scanty or average amount of menses
2. Subjects had a scanty or average amount of menstruation flow along with associated symptoms.
3. Subjects in the age group of 16 to 30 years.
4. Subjects with a history of (H/O) using analgesics and other drugs during menses for relief of pain.
5. Subjects suffered from painful menstruation for more than 2 cycles in a row.

Exclusion Criteria

1. Subjects under 16 and over 30 years of age.
2. Diagnosed subjects of secondary dysmenorrhea; having organic pathology of the uterus and adnexa; fibroid uterus, pelvic inflammatory disease, ovarian cysts, carcinoma of endometrium, venereal diseases, etc.
3. HIV, VDRL, HBsAg positive subjects.
4. Subjects suffered from Systemic diseases.
5. Subjects using intrauterine contraceptive devices.
6. Subjects suffered from excessive bleeding per vaginum, associated with pain in the abdomen
7. Subjects with H/O thyroid dysfunction.

Criteria for Withdrawal

1. During the course of the trial if any serious condition or any serious adverse effects occurs that need emergency treatment.
2. Subject wanted to withdraw herself from the clinical trial willingly.
3. Subjects with irregular follow-up.

Administration of Drugs

Patients included in the present study were randomly divided into two groups (Table 1). This clinical trial was carried out for two consecutive menstrual cycle, rote of drug administration chosen was oral in both groups, drugs dose and duration is mentioned.

Table 1: Administration of drugs

	Group-A	**Group-B**
Drug	*Vijayadi-vati*	*Ahwagandha choorna*
Dose	250mg two times a day with lukewarm water before taking a meal	5gm twice a day with lukewarm water before taking meal
Route	Oral	Oral
Duration	For two consecutive menstrual cycle	For two consecutive menstrual cycle
Time	7 days before menstrual cycle	7 days before menstrual cycle

Criteria of assessment: Subjective Parameters

Effect of trial drug was assessed mainly on the basis of relief in the signs and symptoms of the disease. To assess the effect of therapy objectively, all the signs and symptoms were given a special scoring depending based upon their severity. Assessment of pain was done on the basis of intensity (Table 2), duration (Table 3), and nature of pain (Table 4). Amount of menstrual flow (Table 5) and Visual Analogue Score also included in scoring system. Other 11 associated symptoms according to Ayurveda as well as per modern, also assessed by the special scoring method. A unique scoring pattern was applied to symptoms and associated complaints. The improvement in the patient was mainly based on relief in the signs and symptoms of the disease.

Assessment of Pain (Dysmenorrhoea)

Table 2: Pain Intensity

Pain Intensity	Grade
No pain	0
Mild (pain do not interfere with day to day activity)	1
Moderate(daily activity hampers, relieves with analgesics)	2
Severe (do not relieve even after taking analgesics)	3

Table 3: Duration of Pain

Duration of Pain	Grade
Absent	0
Pain for few hours	1
Pain for one whole day	2
Pain for>or=2 days	3

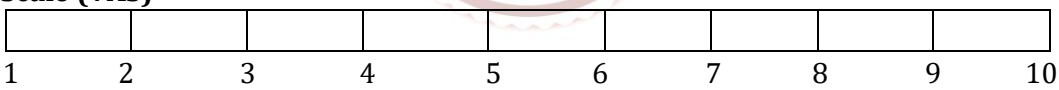
Table 4: Nature of Pain

Nature of Pain	Grade
Absent	0
Occasional (Mild)	1
Dull (Continuous)	2
Spasmodic (Cramp like)	3

Table 5: Amount of Menstrual Flow

Amount of Menstrual Flow (Total No. of pads used during a cycle)	Grade
Scanty (< 9 pads /cycle)	0
Average (9-12pads/cycle)	1
Normal (13-15pads/cycle)	2
Excessive (>15 pads or more)	3

Visual Analog Scale (VAS)



Further it is assessed as follows

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

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

OBSERVATION AND RESULT

Clinical Improvement: The pattern of clinical improvement in various subjective parameters were recorded and measured statistically in the two groups, which is being presented here in tabular forms.

Table 6: Inter group comparison of 'Subjective Parameters' of *Kashtartava* by Mann-Whitney Test

Symptoms	Group	Mean Dif.	S.D.±	S.E.±	P	Result
Pain Intensity	Group A	2.000	0.6547	0.1690	< 0.01	V.S.
	Group B	1.133	0.7432	0.1919		
Pain Duration	Group A	1.933	0.7988	0.2063	> 0.05	N.S.
	Group B	1.333	0.7237	0.1869		
Nature of Pain	Group A	1.800	0.6761	0.1746	> 0.05	N.S.
	Group B	1.400	0.6325	0.1633		
Flow Amount	Group A	0.06667	0.5936	0.1533	> 0.05	N.S.
	Group B	0.4000	0.7368	0.1092		
Associated Symptoms	Group A	1.533	0.6399	0.1652	> 0.05	N.S.
	Group B	1.400	0.7368	0,1902		
VAS Scale	Group A	2.000	0.9258	0.2390	< 0.01	V.S.
	Group B	0.9333	0.7988	0.2063		

Non-significant results were obtained in Pain Duration, Nature of Pain, Flow Amount and associated symptoms. While highly significant result obtained in pain intensity and VAS Scale in which Group A is better than Group B. (Table 6)

Table 7: Inter group comparison on 'Associated Symptoms' of *Kashtartava* by Mann-Whitney Test

Symptoms	Group	Mean Dif.	S.D.±	S.E.±	P	Result
Nausea	Group A	0.6667	0.4880	0.1260	> 0.05	N.S.
	Group B	0.3333	0.4880	0.1260		
Vomiting	Group A	0.2667	0.4577	0.1182	> 0.05	N. S
	Group B	0.2667	0.4577	0.1182		
Fatigue	Group A	0.7333	0.4577	0.1182	> 0.05	N.S
	Group B	0.7333	0.4577	0.1182		
Headache	Group A	0.2667	0.4577	0.1182	> 0.05	N.S
	Group B	0.3333	0.4880	0.1260		
Fainting	Group A	0.1333	0.3519	0.09085	> 0.05	N.S
	Group B	0.1333	0.3519	0.09085		
Sweat	Group A	0.4000	0.5071	0.1309	> 0.05	N.S
	Group B	0.5333	05164	0.1333		
Diarrhoea	Group A	0.1333	0.3519	0.09085	> 0.05	N.S
	Group B	0.06667	0.2582	0.06667		
Constipation	Group A	0.4667	0.5164	0.1333	> 0.05	N.S
	Group B	0.2667	0.4577	0.1182		
Vaginal Discharge	Group A	0.06667	0.2582	0.06667	> 0.05	N.S
	Group B	0.1333	0.3519	0.09085		
Breast Tenderness	Group A	0.6000	0.5071	0.1309	> 0.05	N.S.
	Group B	0.4667	0.5164	0.1333		
Giddiness	Group A	0.6667	0.4880	0.1260	> 0.05	N.S.
	Group B	0.4000	0.5071	0.1309		

Non-significant results were obtained in both groups. That shows that results in both groups were almost same (Table 7)

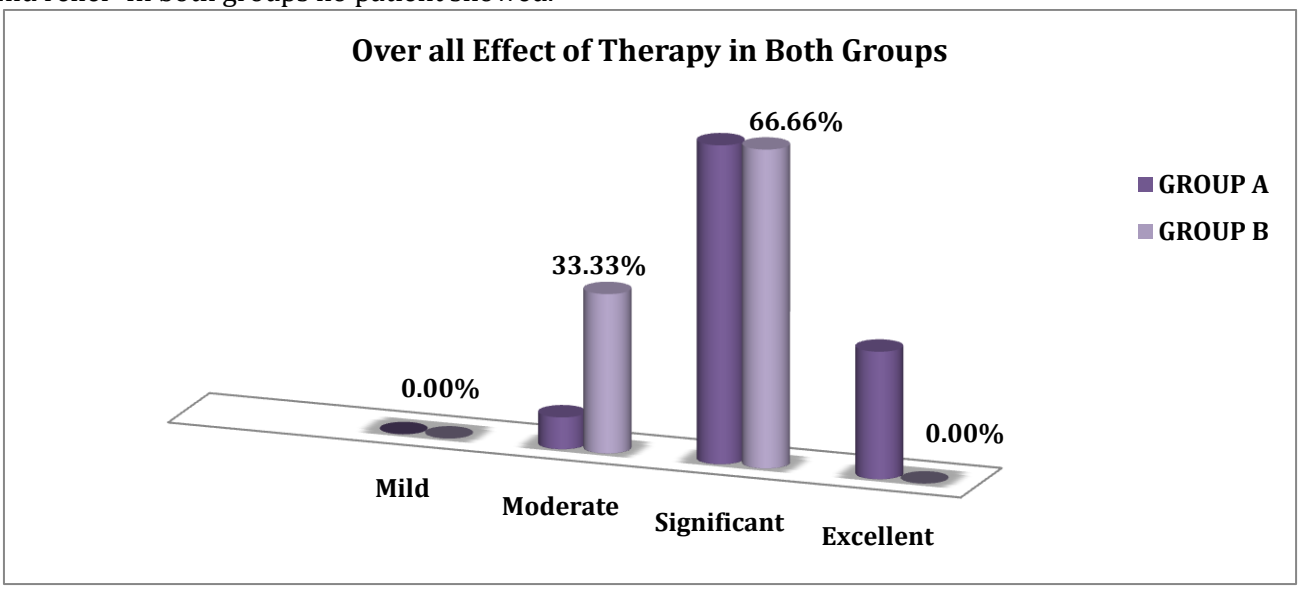
Table 8: Shows the % improvement of symptoms in both groups

S.No.	Cardinal Symptoms	Result in Percentage	
		Group A	Group B
1.	Pain Intensity	83.33%	53.91%
2.	Pain Duration	82.85%	54.03%
3.	Nature of Pain	71.06%	60.00%
4.	Flow Amount	04.54%	26.66%
5.	Associated Symptoms	74.16%	70%
6.	VAS Scale	76.92%	62.14%
7.	Nausea	83.33%	79.99%
8.	Vomiting	66.67%	50.00%
9.	Fatigue	84.60%	78.57%
10.	Headache	66.66%	85.7%
11.	Fainting	49.98%	66.65%
12.	Sweat	75.00%	79.99%
13.	Diarrhoea	66.65%	50.01%
14.	Constipation	58.33%	50.00%
15.	Vaginal Discharge	50.01%	39.99%
16.	Breast Tenderness	75.00%	70.00%
17.	Giddiness	83.33%	50.00%
	Average % of relief	67.78%	60.44%

Compared percentage relief in cardinal symptoms and associated complaints in both groups is mentioned in Table 8.

Overall effect of therapy was more in Group A in comparison to Group B. (Figure 02)

- Excellent reliefs - In group A, 04 patients showed while in group B, no patient showed excellent relief.
- Significant relief- In group A, 10 patients showed f while in group B, 10 patients showed significant relief.
- Moderate relief - In group A, 01 patient showed while in group B, 05 patients showed moderate relief.
- Mild relief- In both groups no patient showed.



Graph 1: Overall Effect of Therapy in Both Groups

DISCUSSION

Summary of key findings: According to Ayurveda, Menstruation is a phenomenon controlled and governed by *Vata,* specifically the *Apana-vayu.* Normal menstruation is a function of *Apana-vata*, so painful menstruation can be considered *Apanavayu-dushti* (vitiation of *Apanavayu*). For the production and expulsion of *Artava* (menstrual blood)*, Vyana* and *Apana vata* work in coordination with each other. *Vyana Vata* has control over the muscles which bring about actions such as contraction, relaxation, extension, flexion etc. Excessive or imbalanced amount of prostaglandins secreted from the endometrium is the ultimate causative factor responsible for pain manifestation in primary dysmenorrhoea. Uterine hypercontractility, decreased uterine blood flow and increased peripheral nerve hypersensitivity contribute to pain.[10] Contraction and relaxation of the uterine muscle fibres is the function of *Vyana Vayu* after which menstrual blood is expelled by *Anulomana Kriya* (restores and facilitates the normal physiological direction menstrual blood) of *Apana Vayu*. So, this dysrhythmic contraction caused by prostaglandins ultimately exhibits painful menstruation. Some reports indicate the levels of prostaglandin F2α measured in menstrual fluid from tampons and found to be twice higher in dysmenorrheic as against non-dysmenorrheic women.[11] According to Ayurveda, Normal menstruation should not be associated with any sort of discomfort such as pain, cramps or burning sensation. Hence painful menstruation is a variation from normalcy, which needs medical attention.

Discussion on primary and secondary outcome measures (clinical improvement in both groups)- An attempt is made to explain the statistical results mentioned in Table no 10.

- **Pain Intensity**

  Results on pain intensity were more in Group A it may be concluded that anti-inflammatory[12], analgesic[13] and anti-prostaglandin properties[14] of different contents of *Vijayadi-vati* has contributed to a maximum relief of pain.

- **Pain Duration**

  Results on pain duration were more in Group A it can be explained that the anti-inflammatory, analgesic and anti-prostaglandin properties of different contents of *Vijayadi-vati* have contributed to a maximum relief of pain.

- **Nature of Pain**

  Group A has shown a maximum effect on the nature of pain due to maximum anti-spasmodic[15] properties of components *Vijayadi-vati* i.e*., Kumari* etc.

- **Flow Amount**

  Artav is having *Aagneya* properties so an increase in the amount of flow can be explained by *Samanya[16]* theory because both drugs are having *Ushna veerya* & *Katu vipaka* and it is the line of treatment for *Artavakshaya* (oligo and hypo-menorrhoea).[17]

- **Associated Symptoms**

  Improvement was almost equal in both groups and the difference was minimal because both drugs have *Vata* pacification properties and it is *Vata* vitiation, causing all associated symptoms.

- **VAS Scale**

  It can be explained by the fact that *Vijayadi-vati* as a compound formulation has more results on pain as it is having contents i.e., *Vijya, Kumari* which are having effects like; anti-inflammatory, analgesic, anti-prostaglandins etc.

- **Nausea**

  This result can be justified in such a way; nausea is a feature due to pain in primary dysmenorrhoea, so when pain is relieved, this symptom will automatically disappear and in Group A *Vijayadi vati* has anti-emetic properties.[18]

- **Vomiting**

  Vomiting is a symptom which is found in severe cases but in this clinical trial maximum patients were of moderate severity of the disease. Group A is having better results by having Anti-emetic properties.

- **Fatigue**

  Fatigue is a feature which is found in *Vata* vitiation conditions both drugs are having *Vata-Shamaka* properties probably due to *Ushna virya* and *Katu vipaka.*

- **Headache**

  Headache is symptom of *Vata* vitiation due to obstruction of due channels of *Vata* by *Kapha* and *Pratiloma gati* (opposite movement) of *Vata*. *Ashwagandha-choorna* being *Vata-kapha* pacifier was having better results in this symptom. *Ashwagandha* produces GABA-like activity, which may account for the herb's anti-anxiety effects. GABA (Gamma Amino-butyric acid) is an inhibitory neurotransmitter in the brain. Its function is to decrease neuron activity and inhibit nerve cells from over-firing. This action produces a calming effect.[19]

- **Fainting**

  Fainting was the least observed feature so a better understanding of the effect of drugs on its study of a large sample should be carried out.

- **Sweat**

  Ashwagandha choorna has *Rasayan* (rejuvenating) properties as well as *Vata* pacification sweat, a feature governed by *Vyana vata,* so a highly significant result is due to *Vata prashaman* action (Figure 4). *Ashwagandha* is having action on the excess amount of sweating.[20]

- **Diarrhoea**

  Maximum percentage of relief i.e., 66.65% in Group A which was statistically non-significant (P<0.05), followed by Group B in which the percentage of relief was, 50.01% which was statistically non-significant (P<0.05).

- **Constipation**

  Constipation is a result of *Apan vata* vitiation in Group A due to the *Anulomana* effect of drugs marked relief was observed.

- **Vaginal Discharge**

  As it was the least observed feature so for a better understanding of the effect of drugs on it study on a large sample should be carried out.

- **Breast Tenderness**

  As it is a result of increased inflammatory mediators; prostaglandins and both drugs are having anti-inflammatory properties so the above results were achieved.

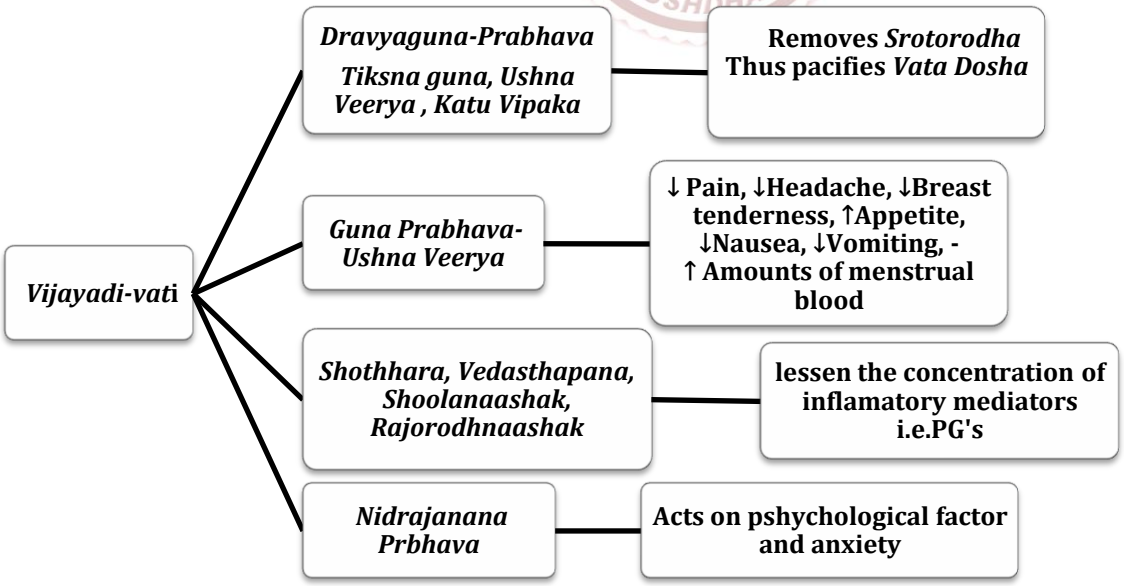
- **Giddiness**

  Giddiness is evident after the effect of pain and as far as the pain subsides it also disappears simultaneously.

Interpretation and Implication: Till date no successful advances have been made in the management of primary dysmenorrhoea by conventional medicine. Primary dysmenorrhoea has not gained much attention because itself it is not having any serious impact on life but it is resulting in the form of missing work or school, inability to participate in sports or other activities. Thereby, it may accentuate the emotional distress brought on by the pain. The problem of absenteeism from school or work is also underappreciated. These two oral drugs were selected as trial drugs as they are palatable, cost effective and can be taken easily with busy life schedule and will impart a permanent cure without side effects.

Probable mode of Action of *Vijayadi-Vati*

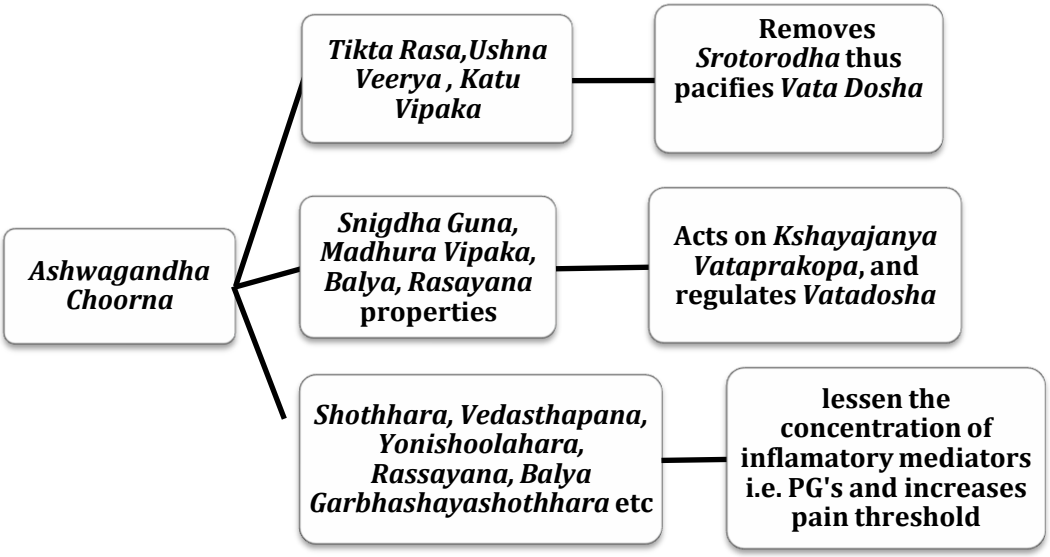
The basic principle of *Kashtartava* treatment revolves around pacifying vitiated *Vata Dosha. Vijayadi-Vati* has a direct reference in *Bhaishajya Ratnavali* for *Kashtartava* (primary dysmenorrhoea).[21] It has *Tikta Rasa, Laghu, Tikshna Guna, Ushna Virya* and *Katu Vipaka.* Along these lines, it removes the *Srotoavarodha* (obstruction of bodily channels) and thus pacifies *Vata's* vitiation. It works by *Dravya Prabhava, Guna Prabhava* and *Dravyaguna Prabhava* respectively. (Figure 3)



(Figure 3)

Probable mode of action of *Ashwagandha-Choorna*

Ashwagandha has anti-prostaglandin effects similar to those of mefenamic acid and ibuprofen.[22]



(Figure 4)

CONCLUSION

This is one of the commonest gynaecological conditions faced by women at their adolescent age; the precious life span of a female. Dysmenorrhoea itself is not a lethal disease in any of its capacities, but it is found to have a huge impact on the daily activities of a female and may result in missing work or school, and the inability to participate in sports or other activities. In *Kashtartava* there is the presence of pain with menstrual blood flow because of the vitiation of *Vayu*. Regulation of *Vayu* plays a key role in treating *Kashtartva*.

After having a basic understating of the pathogenesis of the disease, treatment for *Kashtartava* should be directed towards pacification of *Vata* and carrying off *Vata* by the regular channels. Pacification of *Vata dosha* in form of *Vijayadi-vati* & *Ashwagandha choorna* is highly effective in the disintegration of the pathogenesis of the disease. In form of reducing symptoms, improving quality of life, preventing complications and side effects and above all it was easy to take with a busy life schedule. It was randomized, open, clinical trial and data were collected with full caution and analysed with software GraphPad in stat and with the help of proper statistical test.

Comparing the symptomatic improvement in both groups it was found that the Average percentage of relief was higher in 'group A'– 64.6%, followed by 'group B' i.e., 58.37%. It shows that the effect of therapy was more in group A in comparison to group B.

There were no controversies raised by this study or related with this particular study. No adverse effect of the drug was seen during the present clinical study.

Future Research Directions

1. Further study is suggested to evaluate the prostaglandin levels in menstrual blood in females suffering from primary dysmenorrhoea.
2. Any standard modern medicine should be taken as control group for comparison of the system of medicine.
3. Same study should be conducted with larger sample and with longer duration of trial period with frequent follow up so the rate of recurrence of the disease can also be studied.
4. Study should be carried out with some practical aspects of *Rajaswala charya* (code of conduct during menstruation).

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