ISSN: 2322 - 0902 (P)
ISSN: 2322 - 0910 (O)

International Journal of Ayurveda and Pharma Research

Research Article

A CLINICAL COMPARATIVE EVALUATION OF EFFICACY AND SAFETY OF *KUMARYASAVA* AND *RAJAHPRAVARTANI VATI* IN THE MANAGEMENT OF *PRATHMIK KASTARTAVA* W.S.R. TO (PRIMARY DYSMENORRHOEA): A PROSPECTIVE OPEN LABEL SINGLE CENTER STUDY

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ABSTRACT

Background: Primary dysmenorrhoea is most prevailing symptom in young adolescent girls. It can start before menarche and may be present continuously for years even after the patient get married and have children.

Kashtartava can be expressed as- *"kashten munchyati iti kastartava"* i.e. the condition where *Artava* is shaded with great difficulty and pain is termed as "*Kashtarava*". *Kashtartava* is mentioned as a specific symptom in *Vatala, Paripluta, Udavartini Yonivyapad*, *Vataja Artava Dusti, Kshina Artava-Dusti And Asrigdar* and the diseases in which whole symptomatology denotes *Kashtartava*, are *Pittala, Sannipataki, Suchimukhi Yonivyapada* and *Artavakshaya.*

Aims and objectives: To compare and evaluate the efficacy and safety of *Kumaryasava* with *Rajahpravartani Vati* in the patients suffering from *Prathmik- Kashtartava*.

Material and methods: A prospective open label study was carried out at OPD of Prasuti –Tantra and Stri Roga department. 76 patients satisfying the selection criteria were enrolled, however data of fifty patients was used for analysis and comparative study. 50 patents were divided into two groups (A and B) with twenty five patients in each. Patients of group A were administered *Kumaryasava* 20 ml with equal amount of water and that of group B were administered tab *Rajahpravartini vati* (125 mg) 2BD after meal with normal water before 7 days of menses and during menstrual cycle. Total duration of course of medicine was 3 consecutive cycles. Follow-up was done at every menstrual cycle during the treatment and follow- up without treatment was done for next three cycles. Assessment of intensity of pain was done by VAS and VMSS according to the memory and presentation of the patient. The pain was assessed at baseline and at every menstrual cycle.

Results: After three month of treatment, in both groups the baseline pain was found to be improved in every cycle But when the overall result was observed highly significant results were found in group B in comparison to group A. The effect of *Kumaryasava* on associated symptoms was found to be more than *Rajahpravartini vati*.

Conclusion: *Kumaryasava* and *Rajahpravartani Vati* administered in cases of dysmenorrhea in above mentioned doses were found safe and effective in pain but *Rajahapravartini Vati* showed more effect on overall symptoms of dysmenorrhea including pain and menstrual pattern though *Kumaryasava* was found to be more effective in associated sign and symptoms of dysmenorrhea.

KEYWORDS: *Praathmika Kashtartava*, *Rajapravartani Vati, Kumaryasava.*

INTRODUCTION

The term *Kashtartava* is made of two words *Kashta* and *Artava. Kashtena* - with great difficulty. Thus the word *Kashtartava* can be expressed as:- *"Kashthenamuchyatiiti Kashtartava"* i.e. the condition where *Artava* is shaded with great difficulty and pain is termed as *"Kashtartava"*.[1]

Artava:- A substance of the body which flow out from *Apatya marga* at the specific period of time, without pain, burning and sliminess is called as *Artava.*

In Ayurvedic classics all gynaecological problems are described under the umbrella of *Yonivyapada.* The disease *'Kashtartava'* is not described in classics as well as in *Vedas* as an individual disease entity. Though it is a symptom of various *Yonivapadas* specially *Udavartini*[2], *Vatala, Sannipatika* etc. *Kashtartava* is a *Tridoshajavyadhi* with *Vata* predominance. There is dearrangement of *Apana* and *Vyana Vayu* along with vitiation of *Rasa Dhatu*.

Kashtartava can be compared with dysmenorrhea on the basis of its signs and symptoms.

According to Ayurveda, due to movement of natural urges in reverse direction, the aggravated *Apana Vayu* 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. Ayurveda also describes *Vataja Yonivapad* in which *Ras Dhatukshaya* creates general weakness and cause oligomenorrhoea associated with dysmenorrhoea. When we go through all the conditions, *Samanya Nidan* (the general etiological factors) of *Kashtartava* are found as *Mithya Ahar-Vihar, Artava* and *Bija Dusti, Daiva-Prakop*[6], *Vishamasanshayan,* use of *Apdravyas*[7]. *Vishishta-Nidan* (Specific main etiological factors) can be described with the help of *Nidanas* given for particular disease conditions. The *Samprapti* (pathogenesis) of *Kashtartava* explained that all the three *Doshas* are involved with predominance of *Vata Dosha*.

According to *Acharya Charak* (there are three causes of *Vata Vriddi-Dhatu Kshaya*, *Doshprakop, Margavrodh.*[8]

Due to *Anuloma Dhatu Kshaya*, resulting from *Vata Vardhak Aharvihar, Artavkshaya* occurs as *Artava* is *Updhatu* of *Ras Dhatu.*[9] *Yonivedana* is the cardinal sign of *Artavkshaya*. Apart from that *Dhatukshaya* may turns woman to be *Heen Satva*, where the pain threshold is very less and mild pain is felt very severe.[10]

Dosh Prakopa can be occur in two ways *Swa-Dhatuvaishamya* and *Unmarg-Gaman*,[11] *Acharya Charaka* says that by occupying different seats, vitiated *Vata* produces various disorders with respect to its various etiological factors. This vitiated *Vata* by its *Ruksh, Sheet, Sukshma* properties spread through *Rasavaha* and *Raktavaha Srotus* and further it is responsible for *Artavaha Srotodusti*. *Dosh-Dushya sammurchchhana* takes place in the *Garbhashaya*. Here due to vitiation of *Vyaana* and *Apaana vayu* the normal *Aakunchana* and *Prasaarana kriya* of *Garbhashaya* is affected, which will hinder the normal flow of *Vahipushpa*, resulting in *Kashtartava*, e.g. in *Vataj Yonivyapada* and *Vataj Artavdusti*. In case of *Udavartini Yonivyapada* the functions of *Apaan vayu* gets altered due to *Urdhvagaman* and causes pain.

"Dosha Avrita Margatvata Artavam Nashyati Striyah"[12]. Dalhana has explained that the vitiated *Doshas* are *Vata* and *Kapha* individually and in combined form. In case of *Kaphaavrit Vyaan* pain is an additional symptom which has been stated by *Vangsen* and *Hansrajnidan*. The vitiated *Kapha* due its *Snigdha*, *Guru*, *Pichchhila* and *Abhishyandi gunas* will cause *Jatharagni* and *Dhatvagni Mandya* and that will produce *Ama.* This *Ama Dhatu* causes *Uplepa* over the *Artav-Vaha Srotas* which leads to *Artavapravritti - Avarodh* and *Kastartava.*

Mansik bhava like *Bhaya, Shoka, Chinta, Krodha, Tanava* also aggravates the *Vata* resulting in the same pathology of *Kastartava. Na hi vatadrute shoolam.*[13] V*ata* is the main responsible factor, though other *Doshas* only be present as *Anubandhi* to it.

Dysmenorrhoea is a medical condition of pain during menstruation but more realistic definition includes cases of sufficient magnitude so as to incapacitate daily activities.[14] A pain which is of uterine origin and directly linked to menstruation but with no visible pelvic pathology is called Primary dysmeno-rrhoea. Pain reaches a maximum between ages of 18 and 24 years and thereafter diminishes. The pain is mainly felt in hypogastrium and is often referred to inner and front aspects of the thighs. During a severe attack the patient looks drawn and pale and may sweat; nausea and vomiting are common; there may be diarrhoea and rectal and bladder tenesmus.[15]

Associated complaints of dysmenorrhea were recorded on their presence or absence like nausea, vomiting, headache, dizziness, fainting attacks, constipation or loose motion etc. Amount, colour, consistency and frequency of menstrual blood were also observed to exclude other pathologies. For the assessment of general health screening blood test (HB, TLC, DLC, ESR, RBS, Bl. urea), serum test (HIV, VDRL, HBsAg, Anti HCV) and urine test (routine and microscopic) were done.

Objectives- To evaluate and compare the efficacy and safety of two classical compound *Kumaryasava and Rajahpravrtani Vati* in patients suffering from primary dysmenorrhoea.

MATERIAL AND METHODS

Study design- The study was a prospective open- label single center trial executed at *Rishikul Ayurved* Campus. The study was done in accordance with the good practice guidelines of WHO.

Study participants- Total 70 patient were to be enrolled in trial from the OPD of Prasuti Tantra Evam Stri Roga department. Patients were screened in accordance with the inclusion and exclusion criteria mentioned in the protocol. Total 50 patients following the screening criteria were recruited in the study after obtaining informed written consent.

Inclusion Criteria - married or unmarried female patient aged between 15 and 35 years with average general health and having chief complain of dysmenorrhoea without any pelvic pathology. The range of general screening investigations (blood, serum, and urine) of these patients were found to be in normal limits and who were willing to participate in the study for three months.

Exclusion Criteria

- The patients with low general condition, having abnormal value of screening investigations were excluded from the study.

- Patients who were found to have primary dysmenorrhoea due to imperforated hymen, mullerian duct anomalies like septate, unicornuate or bicornuate uterus, hypo plastic uterus etc.
- Secondary dysmenorrhoea with evidence of any type of pelvic pathology (fibroid uterus, ovarian cyst, endometriosis, pelvic inflammatory disease etc.).
- Patients having done tubal ligation for permanent contraception, patients on contraceptive pills.
- Patients with evidence of malignancy.
- Patients suffering from any other major systemic illness necessitating long term therapy. Alcoholics or drug abusers, lactating women, and patients who have the past record of hypersensitivity to any of the ingredients of the trial medications were also excluded from the study.

Study intervention – Study medications included in group A *Kumaryasava* 20 ml twice a day after meal with equal amount of water and in group B two tablets of *Rajahpravartani Vati* (one tab of 125 mg) twice a day with normal water after meal. In both groups the medicine was administered before 7 days of the date of menstrual cycle. Both Ayurvedic formulations were procured from good manufacturing practice -certified *A*yurvedic pharmaceutical industries and standardised following the standard laid in Ayurvedic pharmacopoeia of India. Patients were also guided for *Pathya- Apathya* and *Yoga* (stabilising exercises).

Study procedure: on the enrollment day at baseline (visit 1), patient's demographic profile, and medical history family history, menstrual history (particularly related to dysmenorrhoea) obstetric history in married patient, patient's *Shariric Prakriti* and vital parameters were recorded. Patient's general, systemic and specifically gynaecological, all examinations were done and findings were recorded. Subsequent visits were planned at the interval of one month or according to the last menstrual cycle of the patient i.e. second visit at next menstrual cycle or 60th day and third visit at about 90th day. Patients were assessed and given study medications at each subsequent visit till 90th day. The patients were further observed for next Three cycles without any medicine. At the study site, data of all patients were recorded in predesigned case report form (CRFs).

Out of the total 76 patients enrolled in the study, 13 dropped out during the study. Intervention to treat analysis was done, and the data of all those patients who have completed at least two cycle visit were imputed by last observation carried forward method (LOCF). Patients who dropped out after baseline visit only were excluded from analysis. Hence data of 50 patients (which were equally divided in two groups i.e. 25 patients in each group) were used for statistical analysis.

Statistical analysis: Symptomatic relief was assessed as percentage change in terms of presence of any symptom at baseline and at 90th day. Visual analogue scale (VAS)[16] questions and Verbal multidimensional scoring system (VMSS)[17] was used to assess the severity of dysmenorrhea. The VAS using a 10- cm line represented the continuum of the female student's opinion of the degree of pain. One extremity of the line represented 'unbearable pain', and the other extremity represented 'no pain at all'. The participants were asked to rate the degree of pain by making a mark on the line. The scores received from the scale were classified into mild dysmenorrhoea if it was between 1–3 points, moderate between 4–7 points, and severe between 8–10 points. The VMSS system was defined as mild, moderate, and severe based on pain and limited activities. Associated symptoms and menstrual pattern was also observed based on percentage change in no of patients.

Table 1: Verbal multidimensional scoring system (VMSS) for assessment of dysmenorrhoea severity

Severity grading	Working ability	Systemic symptoms	Analgesics
Grade 0: Menstruation is not painful and daily activity is unaffected.	Unaffected	None	None required
Mild (Grade 1): Menstruation is painful but seldom inhibits normal activity; analgesics are seldom Required; mild pain.	Rarely affected	None	Rarely required
Moderate (Grade 2): Daily activity is affected; Analgesics required and give sufficient relief so that absence from school is unusual; moderate pain.	Moderately affected	Few	Required
Severe (Grade 3): Activity clearly inhibited; poor effect of analgesics; vegetative symptoms (headache, Fatigue, vomiting, and diarrhoea); severe pain.	Clearly inhibited	Apparent	Poor effect

OBSERVATIONS AND RESULTS

Data of total 50 patients were subjected to statistical analysis. Out of these maximum patients were in age group of 17-20 years. i.e. *Madhyama Awastha* (28% in group A and 24% in group B) and maximum were unmarried (68% in both groups). The *Prakriti* of maximum patients was found to be *Vata-Pittaja* in both groups I.e. 28% in group A and 32% in group B. The demographic profile of the patients in both the groups is given below in (Table 1).

Table – 2. Demographic profile (n = 50) values are expressed in n(%)

Age group in years (*Acharya Harita)*	**GRP- A *Kumaryasava***	**GRP-B *Rajahpravartini vati***
	n=25	**n=25**
10-11 (*Bala*) early age of menarche	2 (8%)	1 (4%)
12 (*Rajaswala*) menarcheal age	1 (4%)	1 (4%)
13-14 *(Bala*) average age of menarche	3 (12%)	3 (12%)
15-16 *(Bala*) delayed age of menarche	4 (16%)	5 (20%)
17- 20 *(Madhyam-Awastha*)	7 (28%)	6(24%)
21- 24,,	4 (16%)	4 (16%)
25-28,,	3 (12%)	2 (8%)
29-32,,	2 (8%)	1 (4%)
33-36,,	0	1 (4%)
37 (end of *Uttama-awastha)* end of best age of fertility	0	1 (4%)
Sex – all female		
Marital status		
Married	8 (32%)	8 (32%)
Unmarried	17 (68%)	17(68%)
Educational status		
Illiterate	1 (4%)	1 (4%)
Read and write	24 (96%)	24 (96%)
Occupation		
Student	13 (52%)	15 (32%)
Working	8 (32%)	8 (32%)
Housewife	4 (16%)	2 (8%)
Socioeconomic status		
Above poverty line	14 (56%)	15 (56%)
Below poverty line	11 (44%)	10 (40%)
Habitat		
Urban	10 (40%)	10 (40%)
Semi-urban	10(40%)	10 (40%)
Rural	05 (20%)	05 (20%)
Sharirik Prakriti		
Vataja	07 (28%)	08 (32%)
Pittaja	05 (20%)	05 (20%)
Kaphaja	00	00

Vata-pittaja	06 (24%)	06 (24%)
Vata-kaphaja	05 (20%)	05 (20%)
Pitta-kaphaja	00	00
Sannipataja	02 (8%)	01 (4%)

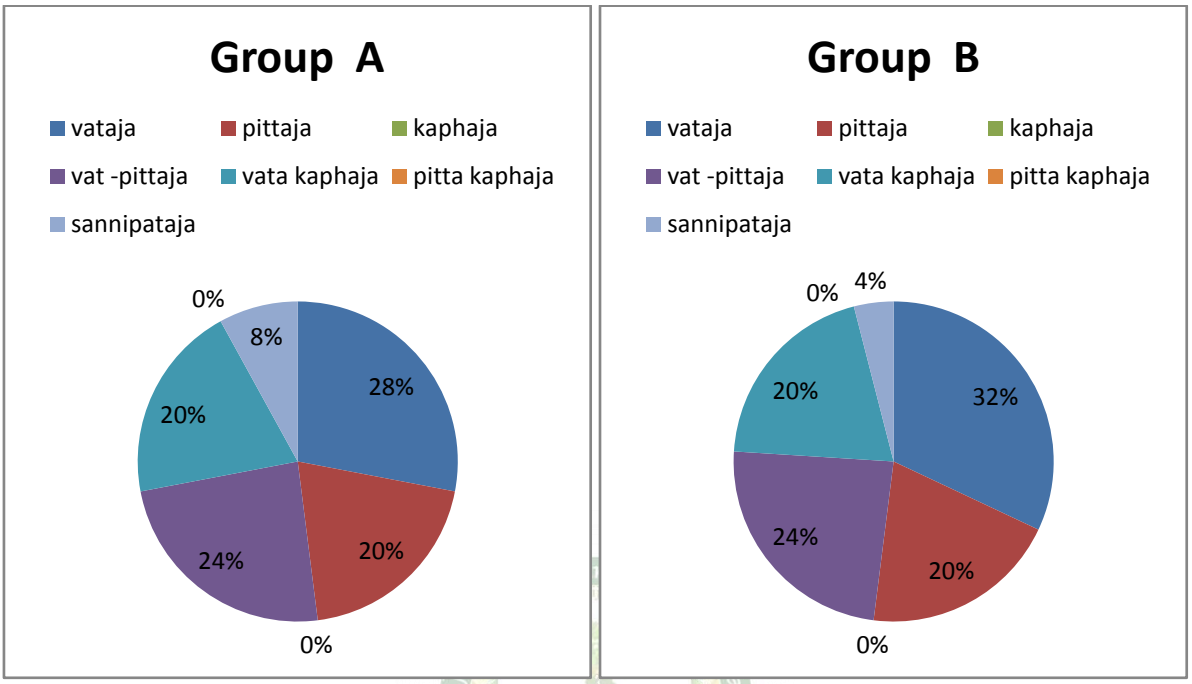

Fig 1. Pie chart for *Sharirik Prakriti* in both the groups

Among the married patients which were 32% in both groups maximum patients were nulliparous 5% in group a and 37.5 % in group B. 87.5% patients in group A and 75% % in group B were having the history of abortions. (Table 3)

Table -3-Distribution of patients according to the obstetric history in married patients

	GRP-A	**GRP-B**
Parity	**n=8**	**n=8**
0	04 (50%)	3 (37.5%)
1	02(25%)	02(25%)
2	01 (12.5%)	01(12.5%)
3	00	01(12.5%)
>3	01(12.5%)	01 (12.5%)
Abortions		
Present	07 (87.5%)	06 (75%)
Absent	01(12.5%)	01(12.5%)
Contraception		
Present (only on barrier methods)	04(50%)	04(50%)
Absent	04(50%)	04(50%)

Regarding the pattern of menstruation it was observed that 32% patients in both groups were having duration of 5-6 days with 25-27 days interval. Amount of bleeding was moderate (5-6 pads /day) in 56% patients in group A and 76% patients in group B. The pain was found in lower back & lower abdomen in 56% patients in group A and 52% in group B. According to visual analogue scale the pain was of moderate type in maximum patients of both the groups (52% of patients). (Table 4)

Table-4-Distribution of patients according to pattern of menstrual cycle —values are expressed in mean (standard deviation)

Duration	**GRP-A**	**GRP-B**
3-4	04 (16%)	05(20%)
4-5	06(24%)	06(24%)
5-6	08(32%)	08(32%)
6-7	07 (28%)	06(24%)
Interval		
25-27days	08(32%)	09(36%)
28-30	04(16%)	04(16%)
31-33	06 (24%)	06(24%)
33-35	07(28%)	06(24%)
Amount of blood		
Normal 3-4 pads in24 hrs	11(44%)	06(24%)
Moderate 5-6 pads	14(56%)	19 (76%)
Colour of blood		
Blackish red	11(44%)	06(24%)
Brownish red	14(56%)	19(76%)
Consistency of blood		
Thick mucoid	08(56%)	05(20%)
Clotted	10(40%)	10 (40%)
Normal	07 (28%)	10(40%)
Onset of pain		
Before7 days up to menses	11 (44%)	11 (44%)
Before 6-5	05(20%)	04(16%)
Before 4-3	04(16%)	04(16%)
Before 2-days	02 (8%)	03(12%)
On first day	03 (12%)	03(12%)
Site of pain		
Low back	03(12%)	03(12%)
Lower abdomen	08(32%)	09 (36%)
Low back and lower abdomen	14 (56%)	13 (52%)
Radiation of pain		
Medial aspect of thighs	22 (88%)	20 (80%)
Leg	03 (12%)	05 (20%)
Severity of pain (according to VAS)		
Mild	04 (16%)	04(16%)
Moderate	13(52%)	13(52%)
Severe	08 (32%)	08 (32%)
Nature of pain		
Pricking	02 (8%)	3 (12%)
Spasmodic with pricking	09 (36%)	09 (36%)
Colicky	14 (56%)	13(52%)

Duration of pain		
Intermittent (stay upto 1-2 min)	09 (36%)	09(36%)
Continuous(didn't relieved without intervention)	16(64%)	16 (64%)
Aggravating factor not relevant		
Relieving factors		
anti-spasmodic or analgesics		
(More frequent dose with injectable)	16(64%)	16(64%)
With normal doses	09(36%)	09(36%)

On gynaecological examination it was found that maximum patients were with healthy cervix without any congestion and abnormal discharges in both the groups (32% of the patients).

Rectal examination was done in unmarried patients to assess the position of the uterus. It was found that maximum patients were having normal sized anteverted uterus. **(Table 5)**

Table-5- Distribution of patients according to gynaecological examination

Per speculum examination in married patients (n=8)	**GRP-A**	**GRP-B**
Healthy cervix without any congestion and abnormal discharges	06(75%)	06(75%)
Healthy cervix with mild hypertrophy and mild watery discharges	02(25%)	02(25%)
Per vaginal examination in married patients (n=8)		
AV nulliparous uterus with non-tender fornix	02(25%)	02(25%)
AV normal size uterus with non-tender fornix	02(25%)	02(25%)
AV parous size uterus with non-tender fornix	02(25%)	02(25%)
RV normal size uterus with non-tender fornix	02(25%)	02(25%)
Per rectal examination in un-married patients		
AV normal size uterus	13(16.25%)	13(16.25%)
RV	04(50%)	04(50%)

Table - 6 Distribution of patients according physical parameters

Parameters	**Group A**	**Group B**
Height (m)		
4ft-4.5ft	08(32%)	08 (32%)
4.6ft -5.5 ft	17(68%)	17 (68%)
Weight (kg)		
45-50	07(28%)	07(28%)
51-55	10(40%)	10(40%)
56-60	05(20%)	05(20%)
61-65	03(12%)	03(12%)
Respiratory rate (per minute)		
15-16	06(24%)	06(24%)
17-18	09(36%)	09(36%)
19-20	03(12%)	02(08%)
21-22	02(08%)	03(12%)
Pulse rate (per minute)		
60-70	05(20%)	05(20%)
71-80	09(36%)	08(56%)

81-90	16(64%)	17(68%)
Blood pressure (mm Hg)		
Systolic		
90-100	08(32%)	07(28%)
101-110	08(32%)	09(36%)
111-120	06(24%)	07(28%)
121-130	03(12%)	02 (08%)
Diastolic		
60-70	10(40%)	10(40%)
71-80	12(48%)	11(44%)
81-90	03(12%)	04(16%)

Table-7 Distribution of patients according to laboratory parameters—values are expressed in mean

Parameters	**Group A**	**Group B**
Hb%	10.8 gm\dl	11.4 gm\dl
TLC	3200.00 cells\cumm	3600.00 cells\cumm
DLC		
Polymorphs	52 %	50 %
Leucocytes	42%	38%
Eosinophyls	2 %	2 %
Monocytes	4 %	4 %
ESR	16	18
Bl sugar	98 gm\dl	76 gm\dl
Liver profile		
Sr total bilirubin	0.10 mg\dl	0.30 mg\dl
SGOT	0.20 mg\dl	0.25mg\dl
SGPT	34.00 mg \dl	36.00 mg \dl
Sr albumin	7.30 g\dl	6.40 g\dl
Sr globulin	4.20 g\dl	3.5 g\dl
Sr alkaline phosphatase	200.00 U\L	170.00 U\L
Kidney profile		
Bl urea	20.8	19.4
Sr creatinine	0.8	0.8
Sr uric acid	3.7	3.6

Table - 8 Effect of treatment on severity of dysmenorrhea according to the verbal multidimensional scoring system (VMSS) in group A and group B

	Group A			**Group B**		
Grading	**Baseline (BT)**	**After treatment**	**Following treatment**	**Baseline (BT)**	**After treatment**	**Following treatment**
Mild	5 (20%)	19(56%)	15(60%)	6(24%)	18(72%)	18(72%)
Moderate	12(48%)	4(16%)	7(28%)	14(56%)	6(24%)	5(20%)
Severe	8(32%)	2(8%)	3(12%)	5(20%)	1(4%)	2(8%)

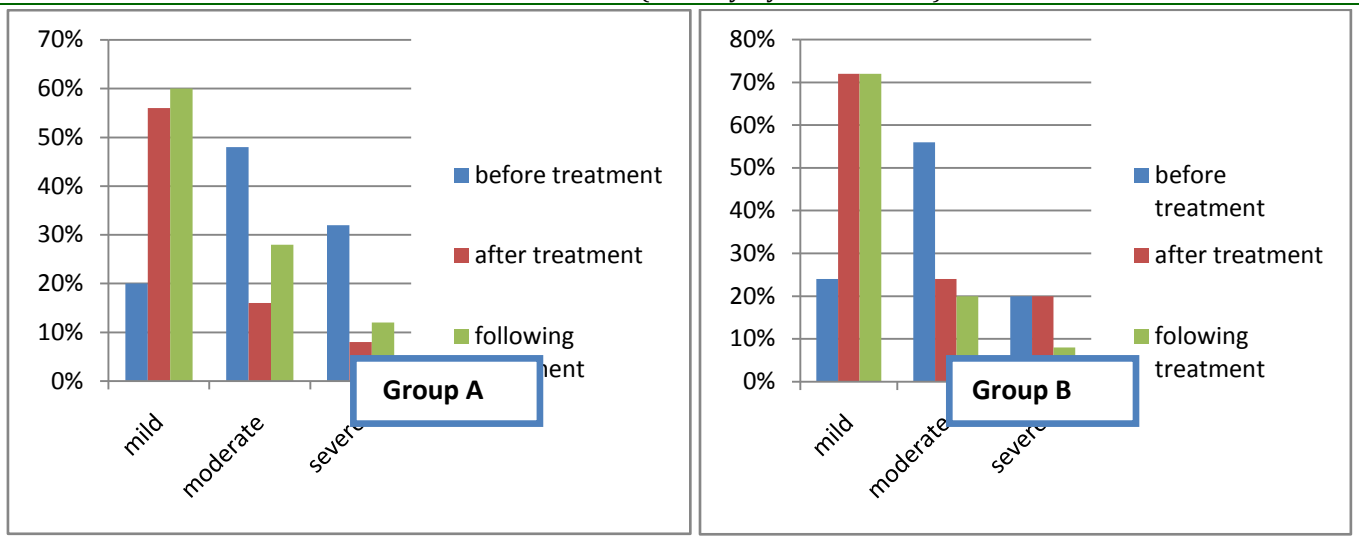

Fig 2. Effect of treatment on severity of dysmenorrhea according to the verbal multidimensional scoring system (VMSS) in group A and group B

Effect of treatment on important characteristics of dysmenorrhea in group A and group B (Table 9) Onset In relation with menstruation when pain starts

In group A *(Kumaryasava*) initially 40% patients were having onset of pain before 12 hours which reduced to only 12 % after treatment and following treatment. Thus after completion of treatment and following treatment most of the patients were having pain only just 4-1 hours before the onset of menstruation.

In group B *(Rajahpravartini Vati*)initially 36% patients were having onset of pain before 12 hours which reduced to only 16 % after treatment and following treatment and after completion of treatment and following treatment maximum patients were having pain 4-1 hours of onset of menstruation.

Thus it was found that group B patients *(Rajahpravartini Vati*) were having more relief in the onset of pain regarding to menstruation (1-4 hours after the onset of menstruation).

Severity of pain (based on VAS score)

In group A *(Kumaryasava*) maximum patients (52%) were having moderate pain according to VAS (Visual Analogue Score) which reduced to only 36 % after treatment and 28% following treatment. And after completion of treatment and following treatment 56% patients were having mild pain abdomen only which was 16 % before treatment.

In group B *(Rajahpravartii Vati*) 48% patients were having moderate pain according to VAS (Visual Analogue Score) which reduced to only 20 % after treatment and 24% following treatment. And after completion of treatment and following treatment 64 % patients were having mild pain abdomen only which was 16 % before treatment.

Thus it was found that group B patients *(Rajahpravartini Vati*) were having more relief in the severity of pain as compared to group A (*Kumaryasava*).

Type of pain: 64 % patients were having intermittent pain initially and following treatment 80% patients were having intermittent type of pain in group A

Effect was found in continuous pain abdomen in group A in 16 % of patients (36 % before treatment and 20 % following treatment).

In group B 32 % patients were having continuous pain abdomen which was found to be in 24 % patients following treatment. Effect of the drug was found only in 8 % patients on type of pain.

Thus more effect was found in group A (*Kumaryasava*) on changing the type of pain to intermittent type from continuous pain.

Duration (for how many days the pain persists)

In group A *(Kumaryasava*) maximum patients (64%) were having pain residing for duration of 1-2days initially which was further reduced to only 12 % of patients after treatment and following treatment. After completion of treatment maximum patients were having pain residing for < 1 days only. Changes were observed in 48 % of patients in reducing the duration of the pain to < 1 days.

In group B *(Rajahpravartini Vati)* 56 % of patients were having pain residing for duration of 1-2 days initially which was further reduced to only 16 % of patients after treatment and following treatment. After completion of treatment maximum patients (64 %) were having pain residing for < 1 days only. Changes were observed in 52 % of patients in reducing the duration of the pain to < 1 days.

Thus more effect was found in group B (*Rajahpravartini vati*) on reducing the duration of pain.

Table 9. Effect of treatment on important characteristics of dysmenorrhea in group A and group B						
Characteristics	**Group A**			**Group B**		
	Before treatment	**After treatment**	**Following treatment**	**Before treatment**	**After treatment**	**Following treatment**
Onset In relation with menstruation when pain starts						
Before 12 hours	10(40%)	3(12%)	3(12%)	9(36%)	4(16%)	4 (16%)
Before 12-9 hours	7(28%)	4(16%)	4(16%)	6(24%)	5(20%)	5(20%)
Before 8-4 hours	4(16%)	4(16%)	4(16%)	3(12%)	1(4%)	1(4%)
Before 4-1 hours	3(12%)	6(24%)	7(28%)	4(16%)	13(52%)	13(52%)
After 1-4 hours	1(4%)	8(32%)	7(28%)	1(4%)	2(8%)	2(8%)
Severity of pain (based on VAS score)						
Mild (1-3)	04 (16%)	14(56%)	14(16%)	4(16%)	16(64%)	15(60%)
Moderate (4-7)	13(52%)	9(36%)	7(28%)	12(48%)	5(20%)	6(24%)
Severe (8-10)	08(32%)	2(8%)	4(16%)	09(36%)	4(16%)	4(16%)
Type of pain						
Intermittent (stay upto 1-2 min)	16(64%)	20(80%)	20(80%)	17(68%)	19(76%)	19(76%)
Continuous (didn't relieved without intervention)	09(36%)	5(20%)	5(20%)	8(32%)	6(24%)	6(24%)
Duration (for how many days the pain persists)						
<1 day	2(8%)	14(56%)	13(52%)	3(12%)	16(64%)	15(60%)
1 day	3(12%)	4(16%)	5(20%)	2(8%)	3(12%)	4(16%)
1-2 days	16	3(12%)	3(12%)	14(56%)	4(16%)	4(16%)
2-4 days	2(8%)	3(12%)	3(12%)	3(12%)	1(4%)	1(4%)
> 4 days	2(8%)	1(4%)	1(4%)	3(12%)	1(4%)	1(4%)

Effect of treatment on associated sign and symptoms of dysmenorrhea in group A and group B (Table 10)

Fever: 60% patients were having associated complaint of fever initially but only 20% and 24% patients were having the complaint of fever after treatment and following treatment respectively in group A.

In group B 60% patients were having associated complaint of fever initially but only 36% and 40 % patients were having the complaint of fever after treatment and following treatment respectively.

The difference obtained is more in group A (*Kumaryasava)* thus *Kumaryasava* is greater effect than *Rajahpravartini vati* on fever.

Anorexia: Severe anorexia was found in 40% of patients before treatment in group A which was reduced to only 8 % patients following treatment. Maximum patients (60 %) were having mild anorexia only following treatment.

In group B also 40% of patients were having severe anorexia initially but it was improved only in 16% of patients i.e., 24 % of patients were still having severe anorexia following treatment. The difference obtained and the improvement was better in group A, thus *Kumaryasava* showed more effect on anorexia.

Nausea: In group A the improvement in nausea was found to be in 16% of patients after treatment while in group B only 9 % of patients showed absence of nausea after treatment. Thus in nausea also *Kumaryasava* worked better than *Rajahpravartini vati.*

Vomiting : Though maximum patients (52 %) were having only mild vomiting before treatment in group A the effect of the drug was obtained on person having moderate vomiting before treatment. Only 20 % of patients were having moderate vomiting following treatment which was found in 48% earlier.

In group B 28 % of patients were having moderate vomiting initially and the difference was obtained only 8% of patients.

The result obtained was better in group A as the effect was found in 28 % of the patients.

Headache: The improvement in headache was found in 32% of patients in group A after treatment while in group B only 20 % of patients showed reduction in

complaint of headache. Thus in headache also *Kumaryasava* worked better than *Rajahpravartini Vati.*

Dizziness: Dizziness was found in 48% of patients before treatment in group A which was reduced to 32 % patients following treatment. Maximum patients (68 %) were having absence of dizziness following treatment.

In group B also 48% of patients were having dizziness initially but it was found only in 24% of patients after treatment and reduced further to 16% of patients following treatment.

Though the effect of the drug was found more in group A it was noticeable that *Rajahapravartini Vati* have greater effect on reducing the symptom following treatment.

Fainting attacks: The improvement in fainting attacks was found in 12% of patients in group A after treatment while in group B only 4 % of patients showed reduction in complaint of fainting attacks. Thus in fainting attacks *Kumaryasava* worked better than *Rajahpravartini Vati.*

Bowel disturbances : marked improvement was found in group A (36 % of the patients) after treatment while in group B changes in bowel disturbances was improved in only 28% of the patients which was less than improvement of group A

Table 10 Effect of treatment on associated sign and symptoms of dysmenorrhea in group A and group B

	Group A			**Group B**		
	Before treatment	**After treatment**	**Following treatment**	**Before treatment**	**After treatment**	**Following treatment**
Fever						
Present occasionally (temp 99-100)	15(60%)	5(20%)	06(24%)	15(60%)	9(36%)	10 (40%)
Absent	10(40%)	20 (80%)	19(76%)	10(40%)	16(64%)	15(60%)
Anorexia						
Mild	06(24%)	15(60%	15(60%	06 (24%)	09(36%)	09(36%)
Moderate	09 (36%)	8(32%)	8(32%)	09(36%)	10 (40%)	10 (40%)
Severe	10(40%)	2 (8%)	2(8%)	10 (40%)	06(24%)	16 (64%)
Nausea						
Present	19 (76%)	03(12%)	03(12%)	19(76%)	10(40%)	11(44 %)
Absent	06(24%)	22(88%)	22 (88%)	06 (24%)	15 (60%)	14 (56%)
Vomiting						
Mild	13 (52%)	20 (80%)	21(84%)	18(72%)	20 (80%)	21 (84%)
Moderate	12(48%)	5 (20%)	4 (16%)	07(28%)	5 (20%)	4 (16%)
Headache						
Mild	14(56%)	22 (88%)	22(88%)	15(60%)	20 (80%)	20 (80%)
Moderate	11 (44%)	3(12%)	3(12%)	10 (40%)	5 (20%)	5()20%
Dizziness						
Present	12 (48%)	8 (32%)	10 (40%)	12 (48%)	6 (24%)	4 (16%)
Absent	13(52%)	17 (68%)	15 (60%)	13 (52%)	19 (76%)	21 (84%)
Fainting attacks						
Present	07	4 (16%)	19 (76%)	5 (20%)	6 (24%)	6 (24%)
Absence	18(72%)	21(84%)	6(24%)	20(80%)	19 (76%)	19 (76%)
Bowel disturbances						
Not present	12 (48%)	21 (84%)	22 (88%)	12 (48%)	5 (20%)	5 (20%)
Present	13 (52%)	4 (16%)	3 (12%)	13 (52%)	20 (80%)	20 (80%)

Duration: no significant changes were obtained in both the groups regarding the duration of menstruation.

Interval: no significant changes were obtained in both the groups regarding the interval of menstruation.

Amount of blood: Initially in group a 28% patients were having scanty bleeding during menses and after treatment 20 % were patients were found with scanty bleeding. Only 8 % of patients showed improvement in bleeding per vaginum, thus *Kumaryasava* have mild effect on improving in the quantity of bleeding.

In group B 28% patients were having scanty bleeding during menses before treatment and after treatment it was found in only 16 % of the patients. Improvement was found in 24 % of the patients, thus showing that *Rajahpravartini Vati* have greater effect on improving amount of bleeding.

Colour of blood: in group A 60 % patients were having blackish color of menstrual blood initially and after treatment only 16 % patients remained with blackish color.

In group B initially 24 % were having blackish color of menstrual blood which was found in only 12 % patients after treatment. Thus *Kumaryasava* showing more effect on improving the color of blood.

Consistency of blood: In group A 28 % were having normal consistency of blood before treatment which increased to 44 % after and following treatment while in group B initially only 40 % patients were having normal bleeding which was further increased to 84 % patients after and following treatment. Changes observed in group A were 16 % and in group B were 44 %. Thus group B *(Rajahpravartini Vati)* showed greater effect on improving the consistency of blood.

Table 11. Effect of treatment on pattern of menstrual cycle

	Group A			Group B		
	Before treatment	**After treatment**	**Following treatment**	**Before treatment**	**After treatment**	**Following treatment**
Duration						
3-4 days	04 (16%)	04(16%)	04 (16%)	05(20%)	05 (20%)	05 (20%)
4-5 days	06 (24%)	06(24%)	06 (24%)	06(24%)	06(24%)	06 (24%)
5-6 days	08 (32%)	08 (32%)	08 (32%)	08 (32%)	08 (32%)	08 (32%)
6-7 days	07 (28%)	07 (28%)	07(28%)	06(28%)	06(28%)	06 (28%)
Interval						
25-27days	08 (32%)	08(32%)	08 (32%)	09 (36%)	09(36%)	09 (36%)
28-30 days	04 (16%)	07 (28%)	07 (28%)	04 (36%)	04 (36%)	04 (36%)
31-33 days	06 (24%)	06 (24%)	06 (24%)	06 (24%)	04(16%)	04 (16%)
33-35 days	07 (24%)	04 (16%)	04 (16%)	06 (24%)	02 (8%)	02 (8%)
Amount of blood						
Scanty (<3 pads in 24 hrs)	7(28%)	5 (20%)	5(20%)	10(40%)	4(16%)	4 (16%)
Normal 3-4 pads in 24 hrs	4 (16%)	6(24%)	6 (24%)	09 (36%)	15 (60%)	15(60%)
Moderate 5-6 pads	14(56%)	14 (56%)	14 (56%)	06 (24%)	06(24%)	06 (24%)
Colour of blood						
Blackish red	15 (60%)	4 (16%)	4(16%)	4 (24%)	3(12%)	3(12%)
Brownish red	8(32%)	7 (56%)	7 (56%)	17 (76%)	4(16%)	4(16%)
Normal menstrual colour	3 (12%)	14 (56%)	14 (56%)	4 (16%)	18 (72%)	18 (72%)
Consistency of blood						
Thick mucoid	08 (32%)	08 (32%)	08 (32%)	05 (32%)	2 (8%)	2 (8%)
Clotted	10 (40%)	6(24%)	6 (24%)	10 (40%)	2 (8%)	2(8%)
Normal	07 (28%)	11 (44%)	11 (44%)	10 (40%)	21(84%)	21 (84%)

DISCUSSIONS

Dysmenorrhea is the common problem in India and most of the patients suffered from severity. Many *Ayurvedic* regimens are described in ancient texts to treat dysmenorrhea considering it as *Doshik* imbalance due to multifactorial etiology. The present study has been conducted to find out an effective treatment for dysmenorrhea. The most common drug in Ayurveda is *Rajahpravartini Vati* prescribed abundantly for dysmenorrhea. We conducted a study to compare the effects of other drug mentioned in classics i.e., *Kumaryasava* with *Rajahpravartini Vati* and to see the effects of both the drugs on pain based on VAS scale, severity on VMSS scale, associated features of dysmenorrhea and pattern of menstrual cycle. On severity of dysmenorrhea more effects were seen in *Rajahpravartini* group. *Kumaryasava* showed more effects on associated criteria of dysmenorrhea. On improving the pattern of menstrual cycle *Rajahpravartini Vati* proved to be more effective.

CONCLUSION

Thus it is concluded that though both the drugs worked in dysmenorrhea their effect was found on different symptomatology. *Kumaryasava* worked in improving the quality of life physically and mentally during the phase of menstruation which was effected by pain and can be given in dysmenorrhea associated with PMS. *Rajahpravartini Vati* affected the pattern of menstruation more than *Kumaryasava* and also showed more effects on decreasing the severity of pain.

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Cite this article as:
Pravesh Tomar, Sudeep Kumar Lal, Saloni Garg. A Clinical Comparative Evaluation of Efficacy and Safety Of Kumaryasava and Rajahpravartani vati in the Management of Prathmik Kastartava w.s.r. to (Primary Dysmenorrhoea): A Prospective Open Label Single Center Study. International Journal of Ayurveda and Pharma Research. 2017;5(11):1-13.
Source of support: Nil, Conflict of interest: None Declared

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