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Research Article

THE MANAGEMENT OF PRIMARY DYSMENORRHOEA (*KASHTARTAVA*) - A PROSPECTIVE MULTICENTRIC OPEN OBSERVATIONAL STUDY

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ABSTRACT

Objective: To evaluate the clinical usefulness of *Rajahpravartini vati* in the management of primary dysmenorrhoea (*Kashtartava*) and changes in the quality of life of the subjects.

Study design: A multi-centric prospective single arm observational study.

Setting and participants: 359 subjects aged between 16 - 35 years suffering from painful menstruation at least for three consecutive regular menstrual cycles were included in the study.

Intervention: *Rajahpravartini Vati* a classical Ayurvedic formulation was administered 250 mg b.d. with lukewarm water for 90 days followed by subsequent 90 days without intervention.

Outcome measures: The management of menstrual pain assessing by 10 points Visual Analogue Scale and improvement in the quality of life using SF-36 (RAND) questionnaire.

Results: The mean VAS score of pain at baseline was 6.94 ± 1.98, decreasing to 1.7 ± 2.22 at 90th day which further decreased and maintained to 1.24 ± 1.9 up to 180th day. Associated symptoms like nausea, vomiting, constipation, giddiness, breast tenderness, diarrhea, headache and fainting were completely relieved. The improvements of quality of life in 8 domains viz. pain, general health, physical functioning, social functioning, emotional wellbeing, energy/fatigue, limitation due to physical health and emotional problems at the end of 90th day of intervention was also significant ($p<0.001$) in comparison to baseline. No adverse event occurred during the treatment period.

Conclusion: *Rajahpravartini Vati* has shown a positive role for the treatment of dysmenorrhoea and to improve the quality of life of the subjects.

KEYWORDS: Primary Dysmenorrhoea; *Kashtartava*; *Rajahpravartini Vati;* Single arm - multicentric - prospective-observational study.

INTRODUCTION

Dysmenorrhoea is a medical condition of pain during menstruation but more realistic definition includes cases of sufficient magnitude so as to incapitate daily activities.[1] A pain which is of uterine origin and directly linked to menstruation but with no visible pelvic pathology is called Primary dysmenorrhoea. 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.[2]

As per Ayurvedic classics, pain occurred in the any part of the body due to aggravation of *Vata dosha* and the main two reasons for it are obstruction in the

passage (*Margavarodha*) or loss of body tissues (*Dhatukshaya*). In certain conditions or gynecological disorders (*Yonivyapad)* like *Vataj Rajodushti, Udavarta* or *Udavartini, Antarmukhi* and *Suchirmukhi Yonivyapad* pain occurred during menstruation. According to *Maharshi Charaka*, in *Udavartini yonivyapad,* menstrual blood is pushed in upward direction by the aggravated *Apana vayu* (the governing force of menstrual force) due to obstruction in its normal flow in *Pakwashaya* (pericolon and pelvic region). 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 dysmenorrhoea.[3, 4]

Population surveys suggest a wide variation in prevalence rate of dysmenorrhoea from studies around the world including India reporting a range between 28% and 71.7%.[5-9] It is reported in a study that Dysmenorrhoea is a common problem in India (79.67%) and most of them (37%) suffered regularly from dysmenorrhoea severity.[10]

In conventional system, drug therapy includes Prostaglandin Synthetase Inhibitors for pain management. However, their use is contraindicated in women with GI ulcers, bronchial asthma. Side effects include nausea, vomiting, diarrhoea, abdominal pain, constipation, heart burn and dizziness. Other drugs include hormone therapy and calcium channel blockers. [11]

To regulate uterine contractions and uterine tone, many effective Ayurvedic regimens are described in Ayurvedic classics and various studies have also been conducted; but a proper statistical analysis and interpretation are not available. Appropriate and validated parameters are lacking for assessment of efficacy of the drugs in some of these studies and sample size was also less to draw a conclusion. Further, health related quality of life has not assessed in any study. [12-15]

Keeping this in view, this study was carried out on well known and safe classical Ayurvedic formulation *Rajahpravartini vati* that is being successfully prescribed by Ayurvedic physicians since centuries.

OBJECTIVES

The primary objective of this study was to establish the therapeutic usefulness of an Ayurvedic compound formulation- *Rajahpravartini Vati* in the management of primary dysmenorrhoea (DYS). The secondary objective was to assess the changes in the quality of life of the patients of DYS and to make ascertain the clinical safety of *Rajahpravartini Vati*.

MATERIAL AND METHODS

Study design

This was a multi-centric prospective observational study. The patients were recruited between March, 2011 and August, 2012 from 09 central and regional Institutes of Council for Research in Ayurvedic Sciences (CCRAS) viz. Ayurvedic Central Research Institute, Delhi, Nagpur and Jaipur; Ayurvedic Contraceptive Drug Research Institute, Ahmedabad; National Ayurvedic Dietetics Research Institute, Bengaluru; Dr. Achanta Laxmipati Research Centre for Ayurveda, Chennai; National Research Institute for Panchakarma, Cheruthuruthy; Ayurveda Regional Research Institute, Jammu and Ayurvedic Research Institute for Mother & Child health Care, Thiruvanantapuram.

The study was approved by the Institutional Ethics Committee of each participating centre and complied with the Declaration of Helsinki and existing GCP guidelines of the country. All eligible subjects were screened after signing the informed consent form to the approved protocol prior to their enrollment in the study. All Investigators were trained in the protocol before initiation of the trial. The study has also been registered in Clinical Trial Registry of India, CTRI/2015/01/005429.

Inclusion and Exclusion criteria

The women aged between 16 to 35 years suffering from painful menstruation for at least three consecutive regular menstrual cycles (21 -35 days) having normal bleeding were included in the study. Patients of secondary dysmenorrhoea, abnormal reproductive system, pelvic inflammatory disease or any serious systemic disorders likely to influence the menstrual cycle, history of malignancy, hypo and hyperthyroidism, diabetes mellitus, hypertension, women using IUD/oral contraceptive pills, and participating in any other interventional study were excluded from the study. Pregnant and lactating women were also excluded.

Study procedures

At screening visit, subject's demographic profile, medical history, family history particularly related to dysmenorrhoea, menstrual history, *Prakriti* (body constitution) and vital parameters were recorded. At each visit i.e.at baseline, 30th, 60th and 90th day (interventional period) study medication were dispensed and clinical assessment were performed. The clinical assessment and pain intensity also measured at 120th, 150th and 180th day (follow up period without intervention).

Grading System

The intensity of menstrual pain was measured in Visual Analogue Scale (VAS) using a 10 cm line represented the continuum of the opinion of the women on degree of pain. One end of the line '0' represented 'No pain', and another end '10' represented the 'worst pain possible'.

The scores received from the scale were classified into mild, moderate and severe as follows:[16]

Mild menstrual pain	**1-3 points**	Menstruation is painful but seldom inhibits normal activity
Moderate menstrual pain	**4-7 points**	Daily activity is affected
Severe menstrual pain	**8-10 points**	Activity clearly inhibited with associated symptoms viz. headache, fatigue, vomiting, diarrhoea

Health related Quality of life (HRQoL) was recorded at baseline and end of the 90th day by using RAND 36 items Short Form health survey (SF-36) questionnaire. Safety lab assessments were also done at the end of the intervention period.

Patient compliance was monitored by keeping a regular follow up of the patients by personal contact, telephonic/ electronic communication. The investigators used to check the medicine packing for its exhaustion at each visit.

Study population

There was no procedure adopted for determination of sample size. However, a total of 368 patients were enrolled in the study.

Intervention

Rajahpravartini vati (Figure-1) an Ayurvedic classical formulation was prepared as per the standard operative procedures mentioned in Ayurvedic Pharmacopoeia of India (API) and was tested for quality & safety parameters *viz.* heavy metal, aflatoxin, microbials & pesticide residue which was within limit. It was administered in a dose of 250 mg twice a day with lukewarm water for 90 days followed by subsequent 90 days without intervention.

Outcome measures

The primary outcome measure was changes in intensity of menstrual pain was assessed at baseline and every follow up i.e. 30th, 60th, 90th 120th, 150th and 180th day by Visual Analogue Scale (VAS). The secondary outcome measure was HRQoL assessed at baseline and 90th day by using RAND (SF-36) questionnaire. It contains 36 items for assessment of eight health domains: physical functioning, social functioning, role limitations due to physical health, role limitations due to emotional health, vitality, mental health, bodily pain and general health perception and scores for each domain range from 0-100 with higher scores indicating better HRQoL.

Statistical analysis

Subjects who have taken the medicine at least in one follow up after the baseline were analyzed which included all patients with a baseline visit and at least one follow up visit. The data of last follow up visit was considered as the data of subsequent follow up visit up to the end of study period by 'last observation carry forward method (LOCF)' under modified intention-to-treat analysis for missing data. The data of nine subjects was excluded from the analysis as they were reported at baseline only. Further, the data of those subjects who fulfilled the SF-36 (RAND) health survey questionnaire, both at baseline and end of the drug intervention period (90 days), was taken for analysis.

The obtained data were entered and analyzed using the SPSS ver.15.0. Descriptive statistics e.g. frequencies and percentages for categorical variables; means and standard deviations (SD) for continuous variables were used to describe the total study cohort. Pair wise comparison and within subject effects of outcome measures were done by using repeated measures ANNOVA. Paired t-test was carried out for assessing the difference in health status (SF-36 health survey) from baseline to 90th day and demonstrated in a spider figure'. In all the analysis, p-*values* <0.05 were considered significant and *p-values* of the pair wise comparison were Bonferroni adjusted. McNemar's Test was used to know improvement status of the outcome measures and the percentage of cure between the follow ups.

RESULTS

Total 477 subjects were screened according to the inclusion and exclusion criteria of the study protocol for participation in the study and a total of 368 subjects were recruited. All vital parameters and lab safety parameters were performed within one week of the study initiation. The flow of the subjects through the study is shown in Figure-1. This paper reflects the analysis of 359 subjects including 36 subjects who dropped out from the study.

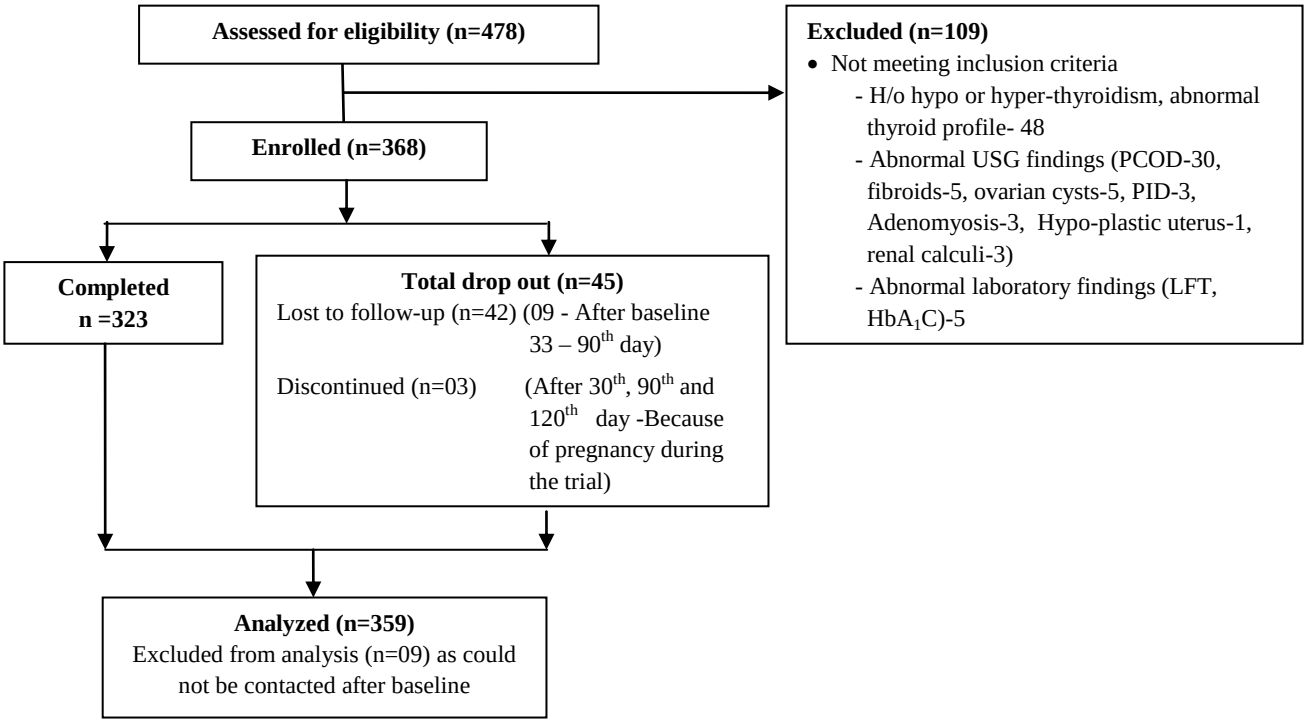

Figure1: Showing flow of patients in the study

The base line characteristics of demographic information: the average age of the subjects was 22.0 ± (5.40) years (range 21-25 years), majority of subjects (62.1%) were students, 82.7 % were having education up to 10th or above. The menstrual pattern (amount and duration of menstrual flow and interval of cycle) was normal in all the subjects. 54.3% (n=159) subjects were having the family history of dysmenorrhoea. Majority of subjects 56.3% (n=202) were having *Pittaj-kaphaja Prakriti*. The more detailed socio-economic and other characteristics of the subjects at baseline are shown in Table-1.

Table 1: Baseline Characteristics of ITT population

Baseline population	n (%)	Mean ± SD
Total patients	359 (100)	
Age (in years)		
• Total	359 (100)	22.0 ± 5.40
• 16-20	177 (49.3)	
• 21-25	101 (28.13)	
Educational status		
• Illiterate	11 (3.1)	
• Upto primary/middle	48 (13.4)	
• Upto 10th /college or above	297 (82.7)	
• Data not available	3 (0.8%)	
Marital status		
• Married	91 (25.30)	
• Unmarried	268 (74.70)	
Non-smoker & non-alcoholic	359 (100)	
Family history of Dysmenorrhoea	195 (54.3)	
Body weight (in kg)		49.14 ± 10.01
Height (in cm)		154.33 ± 5.60
BMI (kg/m^2)		20.63 ± 4.06
Body vitals		
• Pulse rate		74.1 ± 5.4
• Respiration rate		17.0 ± 1.9
Blood pressure (in mm Hg)		
• Systolic		109.1 ± 8.3
• Diastolic		71.71 ± 7.7
***Prakriti* (Predominant)**		
• *Pittaja-kaphaja*	202 (56.3)	
• *Vata-pittaja*	87 (24.2)	

Menstrual history		
• Age of menarche		13.51 ± 1.18
• Duration of menstrual flow		4.48 ± 1.1
• Amount of bleeding/day (in no. pads)		2.41 ± 0.74
• Length of menstrual cycle (in days)		28.95 ± 3.3
Outcome measures:		
Menstrual pain (in VAS)		
• Abdomen	359(100)	
• Low back	312 (86.9)	
• Lower limbs	272(78.8)	
Associated symptoms		
• Nausea	119 (33.1)	
• Vomiting	76 (21.2)	
• Constipation	61 (17)	
• Giddiness	88 (24.5)	
SF-36 (RAND) score		
• Physical functioning		76.9 ± 26.8
• Role Limitations due to physical health		57.56 ± 42.84
• Limitations due to emotional problem		65.83 ± 41.01
• Energy/Fatigue		61.3 ± 19.8
• Emotional well being		69.45 ± 18.01
• Social Functioning		73.5 ± 22.2
• Pain		61.3 ± 21.4
Lab safety parameters		
• Hemoglobin (g/dl)		11.34 ± 1.6
• Blood urea (mg/dl)		17.6 ± 5.20
• Serum creatinine mg/dl)		0.70 ± 0.5
• Serum Glutamic Oxaloacetic Transaminase (SGOT) (IU/L)		20 ± 6.3
• Serum Glutamic Pyruvic Transaminase (SGPT) (IU/L)		18.6 ± 10.0
• Serum Bilirubin Total (mg/dl)		0.53 ± 0.23

ITT – Intention to treat; n - Number of subjects; SD - Standard Deviation
Data are presented in mean± (SD) and number (%)

Effects on symptoms and intensity of disease

There was decreasing trend of mean VAS scores of pain in abdomen during menstrual cycle at each visit for the total study population. The mean VAS score at baseline was 6.94 SD (1.985), decreasing to 4.33 SD (2.63) at 30th day, 2.74 SD (2.47) at 60th day and 1.74 SD (2.22) at 90th day and further decreased and maintained to 1.24 SD (1.90) up to 180th day. The within group change from baseline was significant at all visits ($p<0.001$) (Wilcoxon signed rank test). The decrease from baseline at 90th day was 5.20 (95%Cl 4.78-5.62) and this was maintained during the post treatment period 5.68 (95%Cl 5.25-6.11) up to 180th day (Figure-2).

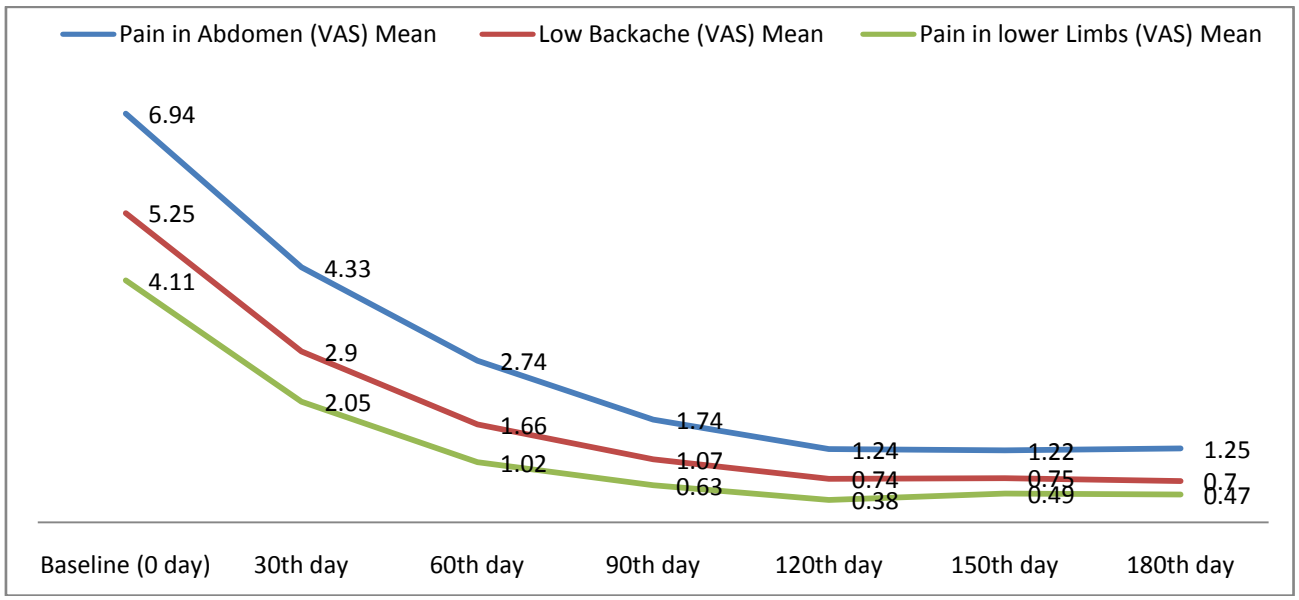

Figure 2: Showing declination trend in pain score of dysmenorrhoic subjects

The subjects also got relief on the associated symptoms like nausea, vomiting, constipation, giddiness, breast tenderness, diarrhea, headache and fainting. The status of patients as relieved/ static/ worse at the end of the intervention and end of the observation period by using McNemar test is presented at Table-2. The data is showing statistically significant changes ($p<0.001$).

Table 2: Overall effect of the trial drug on primary outcome measures

Variables	After intervention period (90th day) (n,%)					End of the period without intervention (n, %)				
	Relieved	Static	Worse	Chi square	P value	Relieved	Static	Worse	Chi square	P value
Pain in abdomen	137 (38.16)	222 (61.83)	0	135.08	<0.01	207 (57.66)	152 (42.33)	0	1.59	0.21
Low Backache	185 (51.67)	167 (46.64)	6 (1.6)	165.88	<0.01	223 (62.11)	133 (37.04)	3 (0.8)	0.09	0.76
Pain in lower limbs	199 (55.43)	155 (43.17)	5 (.01%)	182.59	<0.01	220 (61.28)	133 (37.04)	6 (1.67)	0.108	0.74

Static (No change in score) depicts patients who were either asymptomatic or same as baseline. In McNemar test, only discordant cells are used for data analysis. Accordingly relieved (Complete reduction in score) and worsened (Increase in score from baseline) patients have been considered for analysis.

Changes in health related quality of life

The findings of this study shows that the score received on the various domains of SF-36 scales were improved at the end of 90th day and effect seen were also significant ($p<0.001$) (Figure-3).

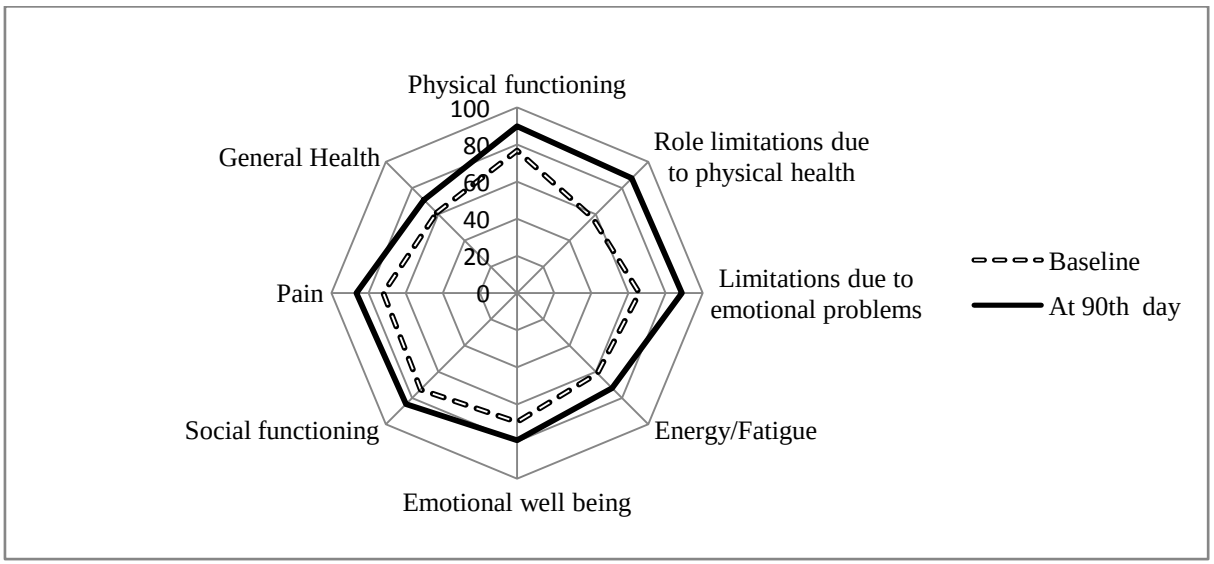

Figure 3: SF-36 (RAND) Health Survey domains

All subjects tolerated the treatment well. None of the subjects developed any adverse drug reaction. There was no remarkable change in any of the safety lab parameters.

DISCUSSION

In this study, the effect of *Rajahpravartini vati* (Figure-4) on primary dysmenorrhoea has been evaluated. There was significant reduction in the menstrual pain and also improvement in the quality of life (physical as well as psychological) of the patients. The reduction of the pain was also stable during the follow up period without administering trial intervention. It proves the long lasting effect of the regimen. Some associated symptoms of primary dysmenorrhoea like nausea, vomiting, giddiness, constipation, diarrhea, fainting reported at baseline were almost completely reduced just after 30th day of the treatment.

Figure 4: *Rajahpravartini vati* (tablet)

In Ayurvedic classics, drugs having carminative, *laxative*, anti-spasmodic properties are indicated in dysmenorrhoea and *Rajahpravartini vati*[17,18] seems to have all properties which help to cure dysmenorrhea. It contains purified *Hingu* (*Ferula asafetida* H.Kar.st), purified *Kaseesa (Ferus sulphate),* purified *Tankana* (borax) and Pulp of *Aloe vera* Linn. in equal quantity which is processed in Juice of *Aloe vera*. *Hingu* is reported to have antispasmodic activity. [19] In one study it was concluded that *Aloe vera* seems to reduce the severity of dysmenorrhea and can be a replacement to non-steroid anti-inflammatory tablets. [20] The mean age of the subjects was 22 years which also validate theory of the age of more prevalence of primary dysmenorrhoea. No adverse effects were reported during study period and no abnormalities were also found in the renal or liver functions. So, this Ayurvedic regimen appears clinically safe. Further, though it is not statistically significant as the patients were instructed not to try for pregnancy during the study period, it is observed that three women having the history of primary infertility got pregnancy during the treatment period. Further, study in this regard is suggested to prove its efficacy on infertility.

There were some limitations in this study. Though the consumption of analgesic was reduced/ not required during the study period but the specific data could not be reported due to inadequate information from the subjects. Further, no comparator group was taken to compare the efficacy of trial drug and prostaglandin was not assessed to know the mechanism of the action of the drug. In future study, these points may be taken into account.

CONCLUSION

This study has provided a clear cut support for clinical use of *Rajahpravartini vati* to treat primary dysmenorrhoea and clinically meaningful improvement of quality of life of the dysmenorrhoic women. However, because of the open label and non-comparative nature of the present study, the findings may further be corroborated through a randomized, controlled study.

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CONTRIBUTION OF AUTHORS

All authors are involved in drafting the manuscript or revising critically the important components and approved the final version to be submitted for publication.

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