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EFFECTIVENESS OF RASNA SWADAMSTRAADI KSHEERAPAKA IN SPASMODIC DYSMENORRHOEA

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Abstract

Many women are familiar with the experience of spasmodic dysmenorrhoea (painful menstruation) one of the commonest gynaecological conditions that affects the quality of life. It can be included under udavarthayonivyapat, caused by apanavatavaigunya described in Ayurvedic classics.. Randomized clinical study was conducted in Govt. Ayurveda College Hospital for Women and Children, Poojappura to evaluate the effectiveness of Rasnaswadamstraadiksheerapaakain spasmodic dysmenorrhoea and to compare its result with that of Sukumaramkashayam. Total 30 patients between the age group 15-35 yrs were taken in to the study who had complaints of severe or moderate lower abdominal pain and associated complaints such as low back ache, nausea, vomiting, diarrhoea, head ache and giddiness, and allocated them into two groups. Study group were treated with Rasnaswadamstraadiksheerapaaka and control group with Sukumaramkashayam. Administration of drug starts 10 days before menstruation and continued till 4th day of menstruation for 3 consecutive cycles for study group and control group. Follow up without medicine will be done for next 3 consecutive cycles for both the groups. Results were analyzed and compared statistically. The research drug Rasnaswadamstraadiksheerapaaka had shown effectiveness in controlling pain in spasmodic dysmenorrhoea and associated symptoms, but in the case of vomiting, head ache and diarrhoea it showed less sustained action in follow up period. The control drug Sukumaramkashayam had also shown effectiveness in controlling pain in spasmodic dysmenorrhoea and associated complaints. But in the case of vomiting, head ache and diarrhoea this medicine also showed less sustained action in follow up period.

KeyWords:Udavartha,Apanavatavaigunya;SpasmodicDysmenorrhoea;Rasnaswadamstraadiksheerapaaka,Sukumaram ---------- kashayam.

Introduction

Ayurveda, the Indian "science of life" is an ancient system of healing that sees health as our birth right. It is a system which uses the inherent principles of nature, to help maintain health in a person by keeping the individuals" body, mind, and spirit in perfect equilibrium with nature. As reproduction is the fundamental requirement for the maintenance of human life, Ayurveda elucidate due importance for the care of mother at every phase of her life. Menstruation is considered as a land mark of homeostatic condition of reproductive system. The same menstruation can create hell situation, if it is associated with unbearable pain as we are observing in cases of dysmenorrhoea.

Spasmodic dysmenorrhoea is one of the most common gynaecological complaints affecting more than 70% of teenagers and out of this 30-50% of menstruating women suffers from varying degrees of discomfort. This situation not only has a significant effect on quality of life and personal health but also resulting in loss of work hours and depression. Absenteeism from work and school as a result of dysmenorrhoea is common. About 13% to 51% women have been absent at least once and 5% to 14% are often absent owing to the severity of symptoms. In the classics of Ayurveda painful menstruation find its role as a sole symptom in *Udavartha yoni vyapath.*

Rasnaswadamstraadiksheerapaaka mentioned for *yoni sula*by achary as Vagbhata and Charaka under *yoni vyapathchikitsa* is found to have promising result in treating spasmodic dysmenorrhoea. So this formulation is assumed to be useful in the management of spasmodic dysmenorrhoea. So the study was conducted to prove the effectiveness of the research drug, "*Rasnaswadamstraadiksheerapaaka*" in spasmodic dysmenorrhoea, on the basis of statistical analysis. To prove its effectiveness it was compared with a control drug "*Sukumaramkashayam"* which is already proven in relieving this condition.

Materials and Methods

TheStudy design was randomized controlled parallel open design in which concurrent control is a positive control. Study population includes: females of age group 15-35 years who are diagnosed as spasmodic dysmenorrhoea fulfilling the inclusion criteria.

Patients with irregular menstruation, having structural deformity of reproductive system known cases of DUB and diagnosed cases of congestive dysmenorrhoea were excluded from the study. Sample size was thirty in number with fifty each in study

and control group. Informed consent of the subject was recorded in a preformat designed for the study. Approval from theInstitutional Ethical committee was taken.

Patients diagnosed as spasmodic dysmenorrhoea will be selected from the OPD of prasuthistreeroga and their primary data will be collected by interview, observation, and relevant investigations. Their clinical symptoms are assessed before starting the treatment. They are randomly allocated into two groups-Groups a study group and group B control group. *Rasnaswadamstraadiksheerapaaka* will be given to study group and *Sukumaramkashayam* will be given to control group as per the dose of *kashaya*48 ml twice daily 1 hour before food. Administration of drug starts 10 days before menstruation and continued till 4th day of menstruation for 3 consecutive cycles for study group and control group.

Outcome Variable

- **Lower Abdominal Pain:** Change in the mean score value assessed by visual analogue scale and verbal descriptor scale.
- **Change in Associated Symptoms:** Nausea, vomiting, diarrhoea, low back ache, head ache and giddiness as per verbal descriptor scale.

Study is statistically analysed through descriptive statistics, Wilcox on signed rank test, Mann Whitney U test and conclusions will be drawn.

Data Related to Clinical Picture

Table 1: Percentage Distribution According to Clinical Picture

Presenting Complaints		Study		Control	
		Frequency	Percentage	Frequency	Percentage
Lower Abdominal Pain	Nil	0	0	0	0
	Mild	0	0	0	0
	Moderate	3	20.0	4	26.7
	Severe	12	80.0	11	77.3
Low Backache	Nil	3	20.0	2	13.3
	Mild	2	13.3	2	13.3
	Moderate	4	26.7	2	13.3
	Severe	6	40.0	9	60.7
Nausea	Nil	3	20.0	4	26.7
	Mild	3	20.0	4	26.7
	Moderate	4	26.7	3	20.0
	Severe	5	33.3	4	26.7
Vomiting	Nil	3	20.0	4	26.7
	Mild	4	26.7	2	13.3
	Moderate	5	33.3	6	40.0
	Severe	3	20.0	3	20.0
Headache	Nil	8	53.3	7	46.7
	Mild	5	33.3	7	46.7
	Moderate	2	13.3	1	6.7
	Severe	0	0	0	0
Diarrhoea	Nil	9	60.0	9	60.0
	Mild	4	26.7	4	26.7
	Moderate	2	13.0	2	13.3
	Severe	0	0	0	0
Giddiness	Nil	7	46.7	6	40.0
	Mild	2	13.3	3	20.0
	Moderate	3	20.0	2	13.3
	Severe	3	20.0	4	26.7

Percentage Distribution on the Severity of Lower Abdominal Pain in Study Group

Pain score (Study Group)	BT		AT		AF	
	N	%	N	%	N	%
Grade 0	0	0	10	66.7	1	6.7
Grade 1	0	0	5	33.3	14	93.3
Grade 2	3	20.0	0	0	0	0
Grade 3	12	80.0	0	0	0	0

(*0-nil, 1-mild, 2-moderate, 3-severe)

Before treatment 80% cases presented with severe pain and 20% cases presented with moderate pain in study group. After treatment 66.7% cases were got complete relief from lower abdominal pain and 33.3% cases were having mild pain.After follow up only 6.7 % patients were in the category of complete relief from pain and the rest 93.3% had persistence of mild pain.

Comparison of Effectiveness of Treatment in Control Group

Wilcox on Signed Rank Test	BT - AT	BT-AF
z	3.508	3.573
p	<0.001	<0.001

Here also p value is significant i.e. p<0.001, which means that the treatment is effective in reducing lower abdominal pain during study period and follow up period.

Comparison of Effectiveness on Pain in Both Groups (BT-AT)

Change (BT- AT)	Study Group		Control Group	
	N	%	N	%
No change	0	0.0	0	0
Mild improvement	0	0.0	2	13.3
Moderate improvement	8	53.3	9	60.0
Significant improvement	7	46.7	4	26.7
TOTAL	15	100	15	100.0

Comparison of Effectiveness on Pain in Both Groups (BT-AF)

Change (BT- AF)	Study Group		Control Group	
	N	%	N	%
No change	0	0	0	0
Mild improvement	3	20.0	7	46.7
Moderate improvement	11	73.3	8	53.3
Significant improvement	1	6.7	0	.0
TOTAL	15	100.0	15	100.0

Comparison of Change in Lower Abdominal Pain between Study Group and Control Group		BT-AT	BT-AF
Mann- Whitney U test	Z	1.442	1.674
	p	.149	.094

While comparing the effectiveness of treatment in both groups related to the main complaint, i.e. lower abdominal pain, in the study group 46.7% patients got significant improvement and 53.3 % got moderate improvement. But in control group only 26.7% of the cases got significant improvement and the rest got moderate and mild improvement. After follow up in study group 6.7% and 73.3% got significant improvement and moderate improvement respectively. But in control group none of them got significant improvement, while 53.3% and 46.7% got moderate and mild improvement respectively.

As per Mann- Whitney U test p value after treatment and after follow up (p>.05) showed that both the drugs are equally effective in curing lower abdominal pain.

Considering the effectiveness of treatment in low back ache in control group 60% patients had severe, 13.3% had moderate, and 13.3% had mild low back ache before treatment .None of them presented with severe low back ache after treatment and after follow up period. Though there were only 13.3% patients with absent symptom before treatment, after treatment 40% and after follow up 33.3% cases were presented with no low back ache.

Comparison of Effectiveness on Low Back Ache in Both Groups (BT-AT)

Change (BT- AT)	Study Group		Control	
	N	%	N	%
*No change	3	20.0	2	13.3
Mild improvement	8	53.3	7	46.7
Moderate improvement	4	26.7	6	40
Significant improvement	0	0	0	0
TOTAL	15	100	15	100

(*3 no change in study group and 2 no change cases in control group represents those with no symptom of low back ache even before the treatment)

Percentage Distribution on the Severity of Nausea in Study Group

Nausea *Score (Study group)	BT		AT		AF	
	N	%	N	%	N	%
Grade 0	3	20.0	10	66.7	3	20.0
Grade 1	3	20.0	4	26.7	11	73.3
Grade 2	4	26.7	1	6.7	1	6.7
Grade 3	5	33.3	0	0	0	0

(*0-nil, 1-mild, 2-moderate, 3-severe)

Before treatment 33.3%, 26.7%, 20% case were having severe, moderate and mild nausea respectively, and 20% cases with no nausea at all. After treatment none of the patients were having severe nausea.6.7% with moderate, 26.7% with mild nausea and 66.7% with no nausea at all. After follow up, in more than 70% patients mild nausea still persist and 6.7% with moderate nausea.

Comparison of Effectiveness of Treatment in Study Group

		AT - BT	AF - BT
Wilcox on signed rank test	Z	3.134	2.739
	P	.002	.006

p value after treatment and after follow up were found to be <.05 ,which signifies the effectiveness of the treatment in reducing nausea during study period and follow up period.

Comparison of Effectiveness on Vomitting in Both Groups (BT-AT)

Change (BT- AT)	Study Group		Control Group	
	N	%	N	%
*No change	5	33.3	6	40
Mild improvement	9	60.0	9	60
Moderate improvement	1	6.7	0	0
Significant improvement	0	0	0	0
TOTAL	15	100	15	100

(*out of 5 no change cases in study group 3 cases were not having vomiting before treatment, and out of 6 no change cases in control group 4 cases were not having vomiting before treatment, rest in both group had vomiting before treatment).

Comparison of Effectiveness on Vomiting in Both Groups (BT-AF)

Change (BT- AF)	Study Group		Control Group	
	N	%	N	%
*No change	13	86.7	14	93.3
Mild improvement	2	13.3	1	6.7
Moderate improvement	0	0	0	0
Significant improvement	0	0	0	0
Total	15	100.0	15	100.0

(* out of 13 no change cases in study group 3 cases were not having vomitting before treatment ,and out of 14 no change cases in control group 4 cases were not having vomitting before treatment, rest in both group had symptom before treatment).

Comparison of Change in Vomitting between Study Group and Control Group		BT-AT	BT-AF
Mann- Whitney U test	Z	0.580	0.598
	p	0.562	0.550

As per Mann- Whitney U test p value after treatment and after follow up showed that both treatments have equal effect in treating vomitting.

Comparison of Effectiveness on Head Ache in Both Groups (BT-AT)

Change (BT- AT)	Study Group		Control Group	
	N	%	N	%
*No change	9	60	7	46.7
Mild improvement	5	33.3	8	53.3
Moderate improvement	1	6.7	0	0
TOTAL	15	100	15	100

(* out of 9 no change cases in study group 8 cases were not having the symptom of head ache before treatment and 7 no change cases in control group are the patients with no symptom of head ache before treatment.

Comparison of Effectiveness on Head Ache in Both Groups (BT-AF)

Change (BT- AF)	Study Group		Control Group	
	N	%	N	%
*No change	13	86.7	14	93.3
Mild improvement	2	13.3	1	6.7
Moderate improvement	0	0	0	0
Total	15	100.0	15	100.0

(* out of 13 no change cases in study group 8 cases were not having the symptom of head ache before treatment and out of 14 no change cases in control group 7 cases were not having the symptom of head ache before treatment)

Comparison of Effectiveness on Giddiness in Both Groups (BT-AF)

Change (BT- AF)	Study Group		Control Group	
	N	%	N	%
*No change	9	60	10	66.7
Mild improvement	3	20.0	3	20.0
Moderate improvement	3	20.0	2	13.3
Significant improvement	0	0	0	0
TOTAL	15	100	15	100

(*out of 9 no change cases in study group 7 cases were not having giddiness before treatment and out of 10 no change cases in control group 6 of them were not having giddiness before treatment, rest had giddiness before treatment).

Comparison of Change in Giddiness between Study Group and Control Group		BT-AT	BT-AF
Mann- Whitney U test	Z	-.489	-.489
	p	.663	.713

As per Mann-Whitney U test p value (>.05) after treatment and after follow up period showed that both drugs are equally effective in treating giddiness.

Comparison of Effectiveness on Diarrhoea in Both Groups (BT-AT)

Change (BT- AT)	Study Group		Control Group	
	N	%	N	%
*No change	9	60	9	60
Mild improvement	4	26.7	6	40
Moderate improvement	2	13.3	0	0
TOTAL	15	100	15	100

(* 9 no change cases in study group and control group are the cases with no diarrhoea before treatment)

Comparison of Effectiveness on Diarrhea in Both Groups (BT-AF)

Change (BT- AF)	Study Group		Control	
	N	%	N	%
*No change	14	93.3	15	100
Mild improvement	1	6.7	0	0
Total	15	100.0	15	100.0

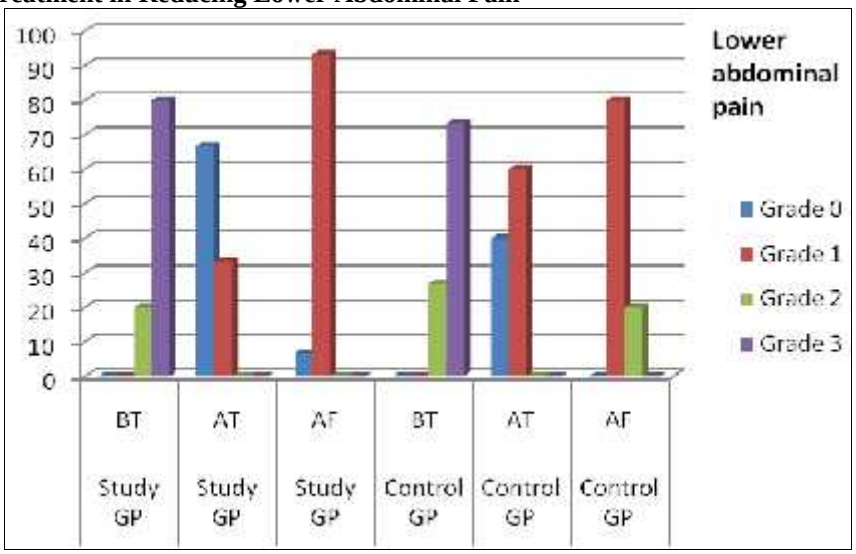
(*out of 14 no change cases in study group 9 cases were not having the symptom of diarrhoea before treatment, and out of 15 no change cases in control group 9 cases were not having diarrhoea before treatment, rest had diarrhoea before treatment).

Comparison of Change in Diarrhoea between Study Group and Control Group		BT-AT	BT-AF
Mann- Whitney U test	Z	-.288	1.000
	p	.773	0.317

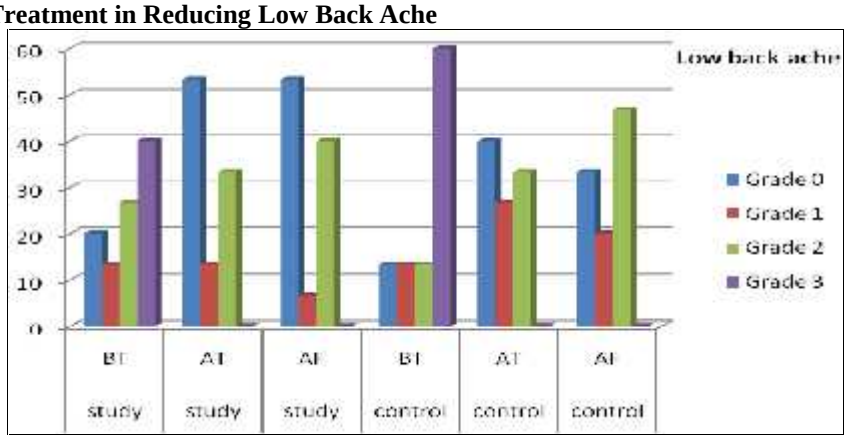
As per Mann- Whitney U test p value after treatment and after follow up showed that both treatments have equal effect in treating diarrhoea.

Figures of Effectiveness of Treatment

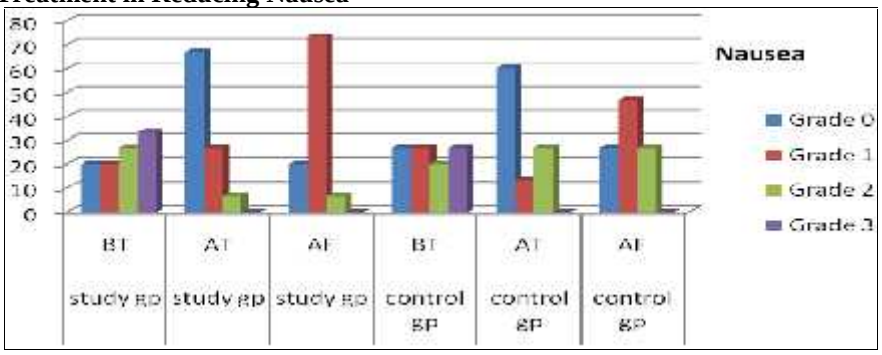
Effectiveness of the Treatment in Reducing Lower Abdominal Pain



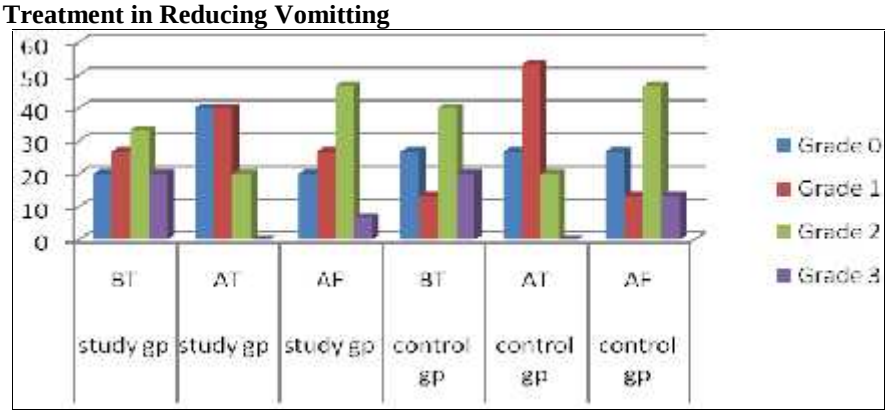
Effectiveness of the Treatment in Reducing Low Back Ache



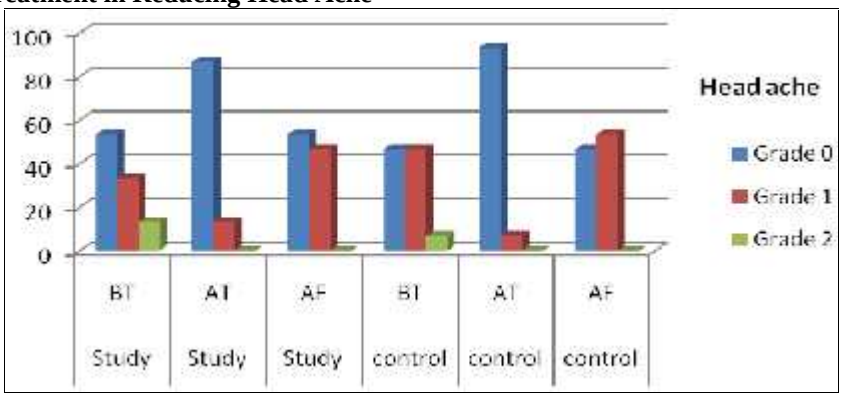
Effectiveness of the Treatment in Reducing Nausea



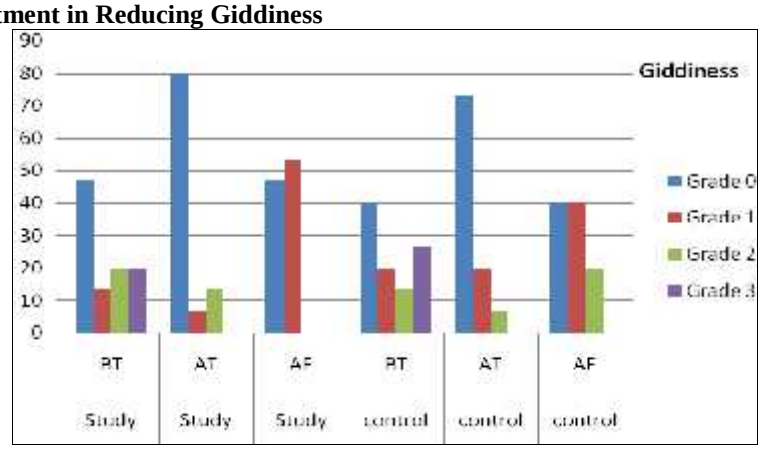
Effectiveness of the Treatment in Reducing Vomitting



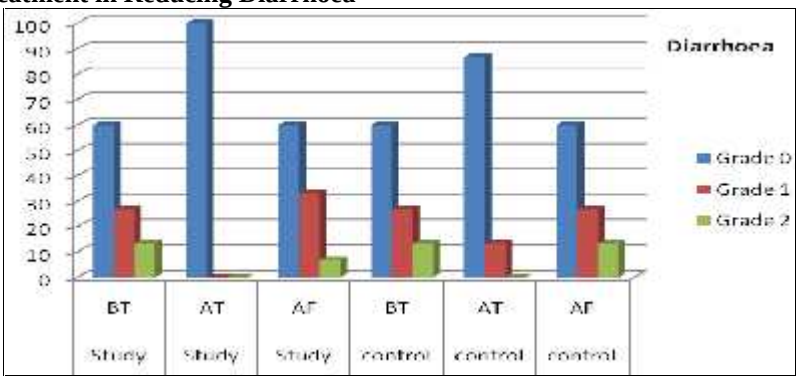
Effectiveness of the Treatment in Reducing Head Ache



Effectiveness of the Treatment in Reducing Giddiness



Effectiveness of the Treatment in Reducing Diarrhoea



Discussion

The classical symptom of spasmodic dysmenorrhoea, lower abdominal pain was taken as the most important parameter for assessing the efficacy of the drug. After treatment in the study group 46.7% patients got significant improvement and 53.3 % got moderate improvement, but in control group only 26.7% of the cases got significant improvement and 60% got moderate improvement. On comparison and statistical evaluation 'p' value showed that both drugs are equally effective in curing lower abdominal pain.

Associated Symptoms

From the analysis on the effectiveness and comparison of both drugs it can be finalized that in controlling the main complaint lower abdominal pain and associated complaints the study drug *Rasnaswadamstraadiksheerapaka* and the control drug *Sukumaramkashaya* were found to be equally effective statistically.

Discussion on Probable Mode of Action of Drug

Before dealing with the action of the drug, we must remind that apanavatavaigunya leading to artavavahasrotodushti causing vilomagati of rajas thereby leads to krchrartavam is the pathogenesis of Udavarta. So the treatment should aim at normalising the apanavata first. There after artavavahasrothoshudhi providing normal expulsion of artava which thereby corrects the pain?

While considering the control drug Sukumaramkashayam, majority of ingredients are having madhurarasa, ushnaveerya and snigdhaguna and hence these can normalise the vitiated vata. Dashamula is the other main ingredient in Sukumarakshayam, and it is anulomana, vatakaphahara, and sothahara. In the case of study drug Rasnaswadamstraadiksheerapaka,which is composed of rasna,swadamstra,vasa and milk only. Rasna is the best vata pacifying drug-vataharanamsreshtam. Being vedanaasthapana and vata pacifier it will remove the margavarodha thereby promoting the normal expulsion of artav resulting in a normal menstrual flow without pain. Swadamstra or gokshura a drug which is having its main action in the genitor urinary system having seethaveerya, tridoshahara and guru snigdhaguna property.It is rasayana, mutrala and vrshya as well Vasais having tiktakashayarasa, seethaveerya and kapha pitta hara property. Many researchers have proved the anti inflammatory and anti spasmodic activity of vasa root, relaxation producing activity and utero tonic activity also.

Milk is a balanced diet containing all the essential nutrients and minerals essential for health. It is jeevaneeya, brmhaneeyarasayanam, and balyam. Calcium deficient musles are more likely to be tense, which may trigger menstrual cramps, so with milk, these drugs acts as an ideal combination for yoni sula.

Conclusion

The research drug Rasnaswadamstraadiksheerapaaka had shown effectiveness in controlling pain in spasmodic dysmenorrhoea by its sulahara, srothorodhanivarana, anulomana, and rasayana property.The control drug Sukumarakashaya had shown effectiveness in controlling pain in spasmodic dysmenorrhoea by its vatakaphahara, srothorodhanivarana and garbhasayashodhana property.

Considering the associated complaints, low back ache, nausea, and giddiness *Rasnaswadamstradiksheerapaka* had shown significant effect in reducing the symptom, but in the case of vomiting, head ache and diarrhoea it showed less sustained action in follow up period.

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