

## Clinical evaluation of shankhapani rasa in the management of kashtartava (dysmenorrhoea)

### Research article

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### Abstract

Menstrual pain which is severe enough to limit normal activities is termed as *Kashtartava* (dysmenorrhoea). Dysmenorrhoea is the most common gynecological problem faced by women due to abnormal anatomical and functional aspect of uterus, pschycosomatic factors, release of prostaglandins, pelvic congestion etc. *Shankhapani Rasa* which is a Herbo-Mineral formulation posses all the contents having *vatahara* and *gulmahara* properties. The clinal Study was carried out to evaluate the efficacy of *Shankhapani Rasa* in patients suffering from *Kashtartava* by selecting 30 patients who attended the O.P.D. and I.P.D. of S.V.Ayurvedic Hospital Tirupathi during the period 2011-2012. Patients were given *Shankhapani Rasa* in a dose of 125mg capsules twice in a day for 1 month randomly and effect was evaluated on pre-test and post-test design. Statistically significant ( $p < 0.01$ ) results were seen in Subjective symptoms like pain during menstruation and duration of pain giving a conclusion that *Shankhapani Rasa* is effective in the management of *Kashtartava*.

**Key words:** *Kashtartava*, Herbo-Mineral, *Shankhapani Rasa*

### Introduction

Menstrual pain which is severe enough to limit normal activities is termed as *Kashtartava* (Dysmenorrhoea). Dysmenorrhoea is pain with menstruation usually craming in nature and centered in the lower abdomen. It is now estimated that almost 50% of all women experience some degree of dysmenorrhoea while 10% were incapacitated by it (1). Severe Dysmenorrhoea is most prevalent in young single women leading sedentary lives and

its incidence becomes higher with the degree of civilization of the community (2). Keeping this in view, it was decided to conduct a study on most prevalent disorder in present times called *Kashtartava*. The drug chosen for the present study is *Shankhapani Rasa*, which was mentioned in *Sahasrayogam, Gutika Yoga Prakaranam*. Here the study is conducted for practical implication and clinical efficacy of *Shankhapani Rasa* in *Kashtartava*.

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### Materials and methods:

- Patients attending the O.P.D. and I.P.D. of S.V.Ayurvedic Hospital Tirupathi were selected.
- The drug *Shankhapani Rasa* was prepared in the Department of R.S &

B.K, S.V Ayurvedic College,  
Tirupathi.

- Total 33 patients with signs and symptoms of dysmenorrhea were registered. Out of which 30 patients completed the course of treatment.

#### **Trial drug:**

The drug chosen for the present study is *Shankhapani Rasa* (3)

**Table Showing the Ingredients of Shankhapani Rasa:**

S. No.	Name of the drug	Quantity Taken (gms)
1.	<i>Suddha Parada</i>	48 (1pala)
2.	<i>Suddha Gandhaka</i>	48 (1pala)
3.	<i>Vatsanabha Churna</i>	48 (1pala)
4.	<i>Hingu Churna</i>	96 (2pala)
5.	<i>Saindhava lavana</i>	384 (8 pala)
6.	<i>Chincha Kshara</i>	384 (8 pala)
7.	<i>Shankha Bhasma</i>	384 (8 pala)
8.	<i>Sunthi Churna</i>	96 (2 pala)
9.	<i>Maricha Churna</i>	96 (2 pala)
10.	<i>Pippali Churna</i>	96 (2 pala)
11.	<i>Nimbu Swarasa</i>	Q.S

#### **Method of preparation:**

*Suddha Parada* and *Suddha Gandhaka* were taken in *Khalwa yantra*. To this *Shodhita Vatsanabhachurna*, *Hinguchurna*, *Saindhava lavana*, *Chincha Ksara*, *Shankha Bhasma*, *Trikatu churna* were added. *Bhavana* was done with *Nimbu swarasa* for one day then dried and filled in 125mg capsules.

#### **Administration of the drug:**

Mode of administration – orally

Dose – 125mg twice in a day

Anupana – Hot water

Duration of t/t- 1 Month (The drug was started Randomly)

Follow up- For 2 consecutive cycles

#### **Protocol: Randomized Open Labeled Clinical Trial protocols**

#### **Plan of study**

#### **Aims and objectives:**

The present clinical study has been planned to evaluate the efficacy of *Shankapani Rasa* in *Kashtartava*.

#### **Statistical criteria:**

Patients were selected by random sampling technique i.e. irrespective of age, caste, religion & occupation, they were advised to visit the hospital every 2 weeks for regular check up & to assess the effect of the therapy there by. In case any patient leaves the treatment without completing 30 days he / she will be declared as dropped out from the research work.

#### **Criteria for inclusion of the patients**

1. Pain during menstruation due to any cause (primary/secondary) except the causes mentioned in exclusion criteria.
2. Regular and Irregular cycles.

#### **Criteria for exclusion of the patients**

1. Rakta pradara (Dysmenorrhea with dysfunctional Uterine Bleeding)
2. Malignancies
3. Surgical conditions.

#### **Investigations:**

Laboratory investigations were carried out before and after treatment to rule out any other pathological conditions as well as to record any specific change by the treatment.

#### **Haematological:**

Routine hematological examinations like total leucocytes count, differential count, hemoglobin percent,

packed cell volume and erythrocyte sedimentation rate (Wintrobe's corrected method).

**Urine:** Routine and microscopic examination.

**Sonography (U.S.G.):** For uterine and adenexal study if needed to rule out any pathology or lesion.

**Criteria for assessment of the result:**

The improvement in the patients 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 scoring depending upon their severity. Dysmenorrhoea, the cardinal symptom assessed on its severity and duration of persistence.

**Assessment of Pain (Dysmenorrhoea): Severity of pain (Multidimensional scoring pattern)**

0	Menstruation is not painful and daily activity is unaffected
1	Menstruation is painful and daily activity is not affected. No analgesic required
2	Menstruation is painful and daily activity is also affected. Analgesic drugs are needed
3	Menstruation is painful, she cannot do even her normal routine work and has to absent from class / office during.No effect even by taking analgesics.

**Duration**

0	No pain in menstruation
1	Pain persists for less than 12 hours
2	Pain continues for 12 -24 hours
3	Pain continues for more than 24 hours

**Subjective criteria: Scoring pattern for general symptoms**

**Table Showing scoring pattern**

None	0
Mild	1
Moderate	2
Severe	3

**Assessment of total effect of therapy:-**

On the basis of improvement in the signs and symptoms of *Kashtartava*, the following criteria were followed to evaluate the total efficacy of the therapy.

**Table showing percentage relief obtained by the Therapy:**

Percentage of relief	Effect
>76%	Cured
51-75%	Markedly improved
26-50%	Improved
<25%	No improvement

**STATISTICAL EVALUATION OF RESULTS**

The obtained information was analyzed statistically in terms of mean score (x), Standard Deviation (S.D.), Standard Error (S.E.). Paired t-Test was carried out at the level of 0.05, 0.01, and 0.001 of P levels. For the more effectiveness of therapy paired t-Test is carried out. The results were interpreted as

a) $P > 0.05$	: Insignificant
b) $P < 0.05$	: Significant
c) $P < 0.01$ & $< 0.0001$	: Highly significant

**Presentation of data:**

The data collected & analyzed has been depicted in the following sequence:

1. General observations viz. age, occupation, religion etc.
2. Results of therapy evaluated on the basis of improvement in symptomatology.

## OBSERVATIONS AND RESULTS

### 1. Age wise distribution:

**Table Showing Age wise distribution of Kashtartava in 30 patients**

S.No.	Age	Number of patients	% of distribution
1.	20-30	15	50
2.	30-40	10	33.33
3.	40-50	05	16.67

Maximum number of patients belongs to age group, 20-30 yrs. (50%), followed by 30-40 yrs (33.3%) and 40-50 yrs (16.67%).

### 2. Religion wise distribution:

**Table Showing Religion wise distribution of 30 patients:**

S.No.	Religion	Number. of Patients	% of Distribution
1.	Hindu	25	83.33
2.	Muslim	05	16.67

Maximum number of patients were Hindus (83.33%) and rest were Muslims (16.67%).

### 3. Marital status wise distribution:

**Table Showing Marital status wise distribution of 30 patients:**

S.No.	Marital status	Number of patients	% of Distribution
1.	Married	20	66.67
2.	Unmarried	10	33.33

Maximum number of patients were married (66.67 %) followed by unmarried (33.33%).

### 4. Nature of work wise distribution:

**Table Showing Nature of work wise distribution of 30 patients**

S.No.	Nature of work	Number of patients	% of distribution
1.	House wife	15	50%
2.	Student	10	33.33%
3.	Labour	5	16.67%

Maximum number of patients were housewives (50 %) followed by students (33.33%), and labourers (16.67%).

### 5. Food habits wise distribution:

**Table Showing Food habits wise distribution of 30 Patients:**

S.No.	Food Habits	Number of patients	% of Distribution
1.	Vegetarian	10	33.33%
2.	Non-vegetarian	20	66.67%

Maximum number of patients were Non Vegetarians (66.67 %) and rest were vegetarians (33.33 %).

### 6. Predominant rasa wise distribution:

**Table Showing the Predominant rasa wise distribution of 30 patients:**

S.No.	Predominant rasa	Number of Patients	% of Distribution
1.	Madhura-Amla	8	26.67%
2.	Lavana-Amla	10	33.33%

3.	Katu-Tikta	12	40%
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Maximum number of patients were habituated to take Katu-Tikta rasa predominant diet (40%), followed by Lavana-Amla rasa (33.33%), Madhura-Lavana rasa (26.67%).

### 7. Constipated Bowel during menstruation wise distribution:

**Table Showing the Constipated Bowel wise distribution of 30 patients:**

S.No.	Constipated Bowel	Number of patients	% of distribution
1.	Present	24	80%
2.	Absent	6	20%

Maximum number of patients had Constipated bowels during menstruation (80 %) and rest (20%) of patients had no Constipated bowels during menstruation.

### 8. Chronicity wise distribution:

**Table Showing the Chronicity wise distribution of 30 patients:**

S.No.	Chronicity	Number of Patients	% of distribution
1.	1-5 yr	12	40%
2.	5-10yr	9	30%
3.	10-15yr	9	30%

Maximum number of patients had been suffering since 1-5 years (40 %), 5-10 years (30 %) and 10-15 years (30 %).

### 9. Parity wise distribution:

**Table Showing the Parity wise distribution of 30 patients:**

S.No	Parity	Number of Patients	% of Distribution
1.	Nulliparous	14	46.66
2.	Primiparous	05	16.67
3.	Multiparous	11	36.67

Maximum number of patients were nulliparous (46.66%) followed by multiparous (36.67%), and primiparous (16.67 %)

### 10. Deha prakruti wise distribution:

**Table Showing the Deha prakruti wise distribution of 30 patients:**

S.No.	Deha prakruti	Number of Patients	% of Distribution
1.	Vata-pitta	17	56.66
2.	Vata-kapha	9	30.00
3.	Kapha-pitta	4	13.33

Maximum number of patients were Vata-pittaja prakriti (56.66%) followed by Vata- Kaphaja prakriti (30.00 %) and Kapha- Pittaja prakriti (13.33 %).

### 11. Family history wise distribution:

**Table Showing the Family history wise distribution of 30 Patients:**

S.No.	Family history	Number of patients	% distribution
1.	Present	12	40%
2.	Absent	18	60%

Maximum number of patients had no family history (60%) and rest had family history (40 %) related to *Kashtartava*.

**12. Regularity of menstrual cycle wise distribution**

**Table Showing the Regularity of menstrual cycle wise distribution:**

S.No.	Regularity	Number of patients	% distribution
1.	Regular	22	73.33%
2.	Irregular	08	26.67%

Maximum number of patients are having regular menstrual cycles (73.33%) and rest are having irregular menstrual cycles (26.67 %).

**13. Onset of pain wise distribution of 30 patients:**

**Table Showing the Onset of pain wise distribution of 30 patients:**

S.No.	Onset of pain	Number of patients	%distribution
1.	Few hours Before menstruation	18	60.00
2.	After menstruation	12	40.00

Maximum number of patients are suffering from pain a few hours before menstruation (60%) and rest are having pain after onset of menstruation (40 %).

**14. Severity of pain wise distribution of 30 patients:**

**Table Showing the Severity of pain wise distribution of 30 patients:**

S.No.	Severity of pain	Number.of patients	%distribution
1.	Grade 1	09	30
2.	Grade 2	13	43.33
3.	Grade 3	08	26.66

Maximum number of patients are having Grade 2 Severity of pain (43.33%) followed by Grade 1 Severity of pain (30%).

**15. Duration of Pain wise distribution of 30 patients:**

**Table Showing the Duration of Pain wise distribution of 30 patients:**

S.No.	Duration of pain	Number of patients	%distribution
1.	< 12 hours	09	30
2.	12- 24 hours	14	46.66
3.	> 24 hours	07	23.33

Maximum number of patients are having 12-24 hrs duration of pain (46.66%) followed by (30%) having <12 hrs duration of pain.

**16. Effect of Shankhapani Rasa on subjective parameters in 30 patients:**

**Table Showing the Effect of Shankhapani Rasa on subjective parameters:**

Symptoms	N	B.T	A.T	Mean	Relief %	S.D	S.E	't'	p
Severity of pain	30	1.966	0.366	1.6	81.35%	0.56	0.102	15.55	0.0003
Duration	30	1.933	0.33	1.6	82.75%	0.674	0.123	12.99	0.0002

This table shows that *Shankhapani Rasa* provided statistically highly significant relief ( $p < 0.01$ ) of 81.35% in Severity of pain and 82.75% relief ( $p < 0.01$ ) in duration.

**Showing the overall Assessment of Clinical trial:**

Result	Number of patients	% patients
Cured	21	70
Moderately cured	06	20
Not cured	03	10

**Discussion:**

Dysmenorrhoea i.e., pain during menstruation is becoming a challenging problem for women. It is commonly prevalent from the age of 16 to 30 years. The present study is under taken to find a complete and safe solution for *Kashtartava* through *Ayurveda*.

*Ayurveda* is an ocean and to take out a pearl i.e., treatment for any ailment is the work of Physician. It is mentioned in *Ayurvedic* classics that physician basing on his knowledge and condition of the patient must decide the drug to be administered. There are various formulations mentioned for treatment of *Kashtartava*. *Shankhapani Rasa* which was mentioned in *Sahasra Yogam* in *Gutika prakarana* consists of *Kajjali*, *Chincha Ksara*, *Trikatu churna*, *Suddha Hingu*, *Suddha Vatsanabha*, *Saindhava lavana* and *Shankha Bhasma*.

Maximum number of patients (83.33%) belonged to Hindu religion. As the Study was conducted in Hindu predominant area, this finding was observed. Eventhough in the present study maximum number of patients (50%) were married, they were having this problem since menarchae. Therefore the relation between marriage and dysmenorrhoea cannot be attributed. It is observed that maximum number, of patients were Housewives (50%). The patients who attended to our hospital were mainly housewives. Maximum number of patients reported in present study were Non-vegetarians (66.67%). Even though it is one of the upashaya of *Kashtartava* as they were taking it only once/twice in a month, it could not decrease the problem in those cases.

It is observed that maximum

number of patients (40%) was taking *Katu-Tikta rasa* predominant *ahara*. This shows the role of *Katu rasa* in the vitiation of *vata*, which is the chief cause in the manifestation of *Kashtartava*. Maximum number of patients (80%) had Constipated bowels during menstruation, this reflects the vitiation of *Apana Vata* which is an important cause for *Kashtartava*. Present study shows that maximum percentage (40%) of patients were suffering from *Kashtartava* since 1-5 years, this shows the chronicity of the disease.

Maximum numbers of patients registered were nulliparous (46.66%). In these cases dysmenorrhoea might be due to the narrow pathway. Incidence according to *prakriti* showed that the majority of patients (56.66%) were *Vata-Pittaja* followed by *Vata-Kaphaja* (30%). This observation supports the involvement of *Vata Dosha* in the pathogenesis of disease. In the present study 40% of patients were shown to have the family history of the disease, hence there might be the possibility of occurrence of the disease in the family.

All the patients were suffering from pain, either, 2-3 hours before the onset of menstruation or during menstruation. This also confirms the diagnosis as Primary dysmenorrhoea.

Statistically highly significant relief of 81.35%, was observed in severity of pain. Statistically highly significant relief of 82.75%, was observed in duration of pain.

*Trikatu* have *deepana*, *pachana* and *shulaprasamana* properties hence it helps in reducing the pain which is produced by *ama* (4). *Vatsanabha* has the properties *madhura rasa*, *ushna virya* and

*madhura vipaka.*, therefore acts as *vata samaka* (5). *Hingu* is having *sula hara*, *Anulomaniya* and *Vata-Kapha hara* properties (6). *Shankha* is having *Sulahara*, *Gulmahara* and *udaramayahara* properties (7). *Saindhava lavana* has *rochana*, *deepana* properties (8). As the *Kshara* is having *lekhana* property it scapes the excessive *doshas* and *dhatu*s from its place and thus helps in relieving the pain which may be due to obstruction of the *srotas* by the *vitiated doshas* (9). *Nimbuka* has *deepana*, *pachana* and *sulahara* properties (10).

### Conclusion:

Clinically the drug *Shankhapani Rasa* was found to cure 70% patients completely without remission of symptoms especially in Severity of pain and duration of pain after cessation of therapy, 20% of the patient had moderate relief in symptoms and only 10% of patients found no relief. Therapy was efficacious on all the major symptoms of the disease.

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