



Research Article

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A CLINICAL STUDY TO EVALUATE THE EFFICACY OF CHATURBEEJ CHURNA AND KAISHORE GUGGULU IN KASHTARTAVA (SPASMODIC AND CONGESTIVE DYSMENORRHEA)

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ABSTRACT

Dysmenorrhea (Dys - difficult, Men -month, Rhein - to flow) -the painful menstruation. 60-70% of women suffer from dysmenorrhea (Kashtartava) out of which 20-25% remains incapacitated for 1-3 days during each cycle but only 5-8% seek medical advice. It is of two types: Primary and secondary dysmenorrhea. It is a common ailment having a major impact over both physical and mental status of women. To find out the best available in Ayurvedic texts, present study was planned to cure the dysmenorrhea with the help of some herbal formulations used orally. For the study 50 patients were selected in a single group out of which 34 were of spasmodic and 16 were of congestive dysmenorrhea. Results were evaluated on basis of improvement in clinical symptoms such as intensity, duration of pain and associated symptoms etc. Subjects were also assessed regarding the intensity of pain on the basis of VAS (visual analogue scale). The data obtained in clinical study before and after treatment was expressed in term of mean, standard deviation (\pm SD) and standard Error (\pm SE). At the end of the period it was found that both the drugs showed marked improvement in the symptoms of spasmodic dysmenorrhea only whereas no improvement was observed in the congestive dysmenorrhea.

Keywords: Kashtartava, Chaturbeej churna, Kaishore guggulu

INTRODUCTION

Puberty is the period during which secondary sexual characteristics develop and capability of sexual reproduction is attained¹. The major landmark of puberty for females is menarche i.e. the onset of menstruation. Menstruation (men-stray-shuhn) is a woman's monthly bleeding commonly known as menstrual cycle. The menstrual cycle is the cycle of natural changes that occurs in the uterus and ovary as an essential part of making sexual reproduction possible. Dysmenorrhea literally means painful menstruation². Some degree of discomfort during menses is observed in most of the women but when it becomes unbearable and affecting the day to day activities then it is called dysmenorrhea. It can be classified into two types- primary and secondary dysmenorrhea. Primary dysmenorrhea refers to one that is not associated with any identifiable pelvic pathology. It affects more than 50% of the post pubescent women in the age group of 18-25 years with ovulatory cycles. Secondary dysmenorrhea refers to one associated with presence of organic pelvic pathology i.e. fibroids, adenomyosis, pelvic inflammatory disease, endometriosis³. Kashtartava is formed of two words- "Kashta and Artava." Kashta means painful, difficult and troublesome. Artava means menstruation. So, the Kashtartava means, "the menstruation occurring with pain." This may affect the health and working capacity of a woman adversely. In Ayurvedic classics all the gynecological problems are described under the umbrella of Yonivyapada. The disease Kashtartava is not described in classics as a separate entity. It is present as a symptom of various Yonivyapadas especially Vatala^{4,5}, Udavartini⁶⁻⁹, Paripluta¹⁰ and Sannipatiki¹¹ etc. It is a Tridoshaja vyadhi with predominance of Vata. Ayurveda which has existed for over 1000 years has always provided a special branch of medicine just for women offering natural and effective alternatives. In the light of modern medicine, the line of

management of dysmenorrhoea is symptomatic and does not provide permanent cure for the disease. Thus, the present study, "A clinical study to evaluate the efficacy of Chaturbeej Churna and Kaishore Guggulu in the management of Kashtartava (Spasmodic and Congestive Dysmenorrhoea)" aims to take care of these complaints with herbal formulations.

Chaturbeej churna has been mentioned in Bhava Prakash Nighantu¹² as vatashamak and shoolhara. Kaishore guggulu¹³ is described as shothhara and tridoshnashak in Bhaishajya Ratnawali.

MATERIALS AND METHODS

Study design: The study was single group open trial conducted between the years 2013-2014. A prior approval of Ethics Committee was obtained before initiation of trial vide IEC/2013/366 dated 10-06-2013. Written and informed consent of the women was taken before the registration for study.

Grouping of the patients: 50 women fulfilling the inclusion criteria were randomly selected into test group for the clinical study. But 4 patients did not turn up and thus dropped out. The patients were diagnosed into spasmodic and congestive dysmenorrhea on the basis of signs and symptoms.

Selection of patients- The patients were selected from OPD/IPD of PTSR Department of R.G.G. P.G. Ayurvedic Hospital, Paprola, irrespective of caste and religion.

Criteria of inclusion

- Patients with the chief complaints of Kashtartava (dysmenorrhoea).

- Patients of age group 15-40 years.
- Married and unmarried.
- Patients willing for the trial.

Criteria of exclusion

- Patient not willing for trial.
- Age group < 15 years and >40 years.
- Patient not fulfilling the inclusion criteria.

- Any other chronic illness - Diabetes Mellitus, hypertension, Fibroid, Endometriosis, Adenomyosis, Malignancies, Congenital anatomical anomalies.
- Pregnancy.
- Allergic conditions, Syphilis, Gonorrhoea, HIV.

Trial drugs

Chaturbeeja Churna
Kaishore Guggulu

Table 1: Ingredients of Chaturbeeja Churna

Name	Botanical name	Part used
Methika	<i>Trigonella foenum graecum</i> Linn.	Beeja
Chandarshoor	<i>Lepidium sativum</i> Linn.	Beeja
Kalajaji	<i>Nigella sativa</i> Linn.	Beeja
Yavani	<i>Trachyspermum ammi</i> Linn.	Beeja

Table 2: Ingredients of Kaishore Guggulu

Name	Botanical name	Part used
Guggulu	<i>Commiphora mukul</i> Hook ex. Stocks	Niryas
Haritaki	<i>Terminalia chebula</i> Retz.	Phala
Bibhitaka	<i>Terminalia bellerica</i> Roxb.	Phala
Amalaki	<i>Emblica officinalis</i> Gaertn.	Phala
Guduchi	<i>Tinospora cordifolia</i> Willd Miers ex Hook. F. & Thoms	Kanda
Pippali	<i>Piper longum</i> Linn.	Phala
Maricha	<i>Piper nigrum</i> Linn	Phala
Shunthi	<i>Zingiber officinale</i> Roxb.	Kanda
Vidanga	<i>Emblica ribes</i> Burm. F.	Phala
Nishotha	<i>Operculina turpethum</i> Linn. Silva Manso	Moola twak
Danti	<i>Baliospermum montanum</i> Muell Arg.	Moola

Determination of Dose

Chaturbeeja churna 3gm B.D with luke warm water.
Kaishore guggulu 500mg tid with milk/luke warm water.

Nature of Administration: 7 days before the onset of period up to 3 days during the period.

Duration of trial: Three consecutive menstrual cycles with monthly follow up at the end of period.

CRITERIA FOR ASSESSMENT

The effect of treatment (results) was assessed regarding the clinical signs and symptoms (on the basis of VAS and grading, scoring system) and the overall improvement.

The criteria adopted for intensity of pain was VAS (Visual Analogue Scale). Visual Analogue Scale (VAS) is measurement instrument that tries to measure a characteristic or attitude that is believed to range across a continuum of values and cannot easily be directly measured. Operationally VAS is usually a horizontal line, 100 mm (10 cm) in length, anchored by word descriptor at each end, as illustrated in figure.

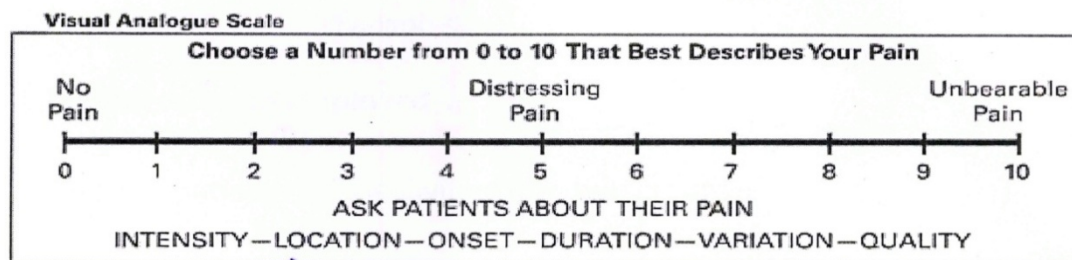


Figure: 1 Visual analogue scale

The patient marks on the line the point that they feel represent their perception of their current state. The VAS score is determined by measuring in millimeters from the left-hand end of the line to the point that the patient marks. The sign and symptoms were assessed by adopting suitable scoring methods. The details are as follow:

Table: 3 Overall score of each symptom

Symptom	Score
Absence of symptom	0
Presence in mild degree	1
Presence in moderate degree	2
Presence in severe degree	3

Table: 4 Scoring according to VAS

Symptom	VAS Score	Final score
No pain	VAS -0	0
Mild pain	VAS 1-3	1
Moderate pain	VAS 4-6	2
Severe pain	VAS 7-10	3

STATISTICAL ANALYSIS

The data obtained in clinical study before and after treatment was expressed in term of mean, standard deviation (\pm SD) and standard Error (\pm SE). Appropriate test like t- test was applied to observe the significance between before and after treatment and regarding inter group comparison of drug effects.

The obtained results were interpreted as:

Insignificant result	p > 0.05
Significant	p < 0.01
Highly significant	p < 0.001

RESULTS AND DISCUSSION

Table 5: Statistical analysis of effect of therapy on Spasmodic dysmenorrhea

Symptoms	N	Mean score		Relief		Paired 't' test			
		B.T.	A.T.	Diff.	In %	S.D. \pm	S.E. \pm	t	P
Duration	32	2.46	0.46	2.0	81.30	0.567	0.100	19.9	<0.001
Intensity	32	2.28	0.46	1.81	79.43	0.535	0.945	19.1	<0.001
Associated features									
Nausea	20	2.40	0.60	1.80	75	0.410	0.091	19.6	<0.001
Vomiting	16	2.43	0.56	1.87	76.95	0.341	0.085	21.9	<0.001
Breast t.	10	2.40	0.30	2.10	87.50	0.567	0.179	11.6	<0.001
Headache	9	2.44	2.00	0.44	81.90	0.500	0.166	12.0	<0.001
Vertigo	4	2.50	0.25	2.25	90	0.500	0.250	9.0	<0.01
Diarrhea	3	2.00	0.00	2.00	100	0.577	3.464	3.4	<0.05
Anorexia	15	2.22	0.53	1.66	75.45	0.487	0.125	13.2	<0.001
Nervousness	2	1.50	0.00	1.50	100	0.707	0.500	3.0	>0.05
Irritability	9	2.11	0.33	1.77	83.80	0.440	0.146	12.0	<0.001
Constipation	9	2.22	0.33	1.88	84.68	0.600	0.200	9.4	<0.001

Table 6: Statistical analysis of effect of therapy on Congestive dysmenorrhea

Symptoms	N	Mean score		Relief		Paired 't' test			
		B.T.	A.T.	Diff.	In %	S.D. \pm	S.E. \pm	t	P
Duration	14	2.07	1.86	0.214	10.35	0.579	0.155	1.38	>0.05
Intensity	14	2.28	2.00	0.29	12.50	0.611	0.163	1.7	>0.05
Associated features									
Nausea	5	2.60	1.20	1.40	53.81	1.140	0.509	2.8	<0.05
Vomiting	0	-	-	-	-	-	-	-	-
Breast t.	5	2.60	1.60	1.00	38.0	0.707	0.316	3.2	<0.01
Headache	6	2.16	1.50	0.66	30.0	0.516	0.210	3.1	<0.01
Vertigo	0	-	-	-	-	-	-	-	-
Diarrhea	0	-	-	-	-	-	-	-	-
Anorexia	6	1.83	0.83	1.00	54.60	0.894	0.365	2.8	<0.01
Nervousness	0	-	-	-	-	-	-	-	-
Irritability	9	2.33	1.77	0.55	23.81	0.726	0.242	2.3	<0.05
Constipation	7	1.85	1.14	0.71	38.59	0.755	0.285	2.5	<0.05
Signs									
Cervical congestion and hypertrophy	14	2.00	1.71	0.285	14.25	0.612	0.163	1.7	>0.05
Cervical motion tenderness	14	2.07	1.92	0.14	7.00	0.363	0.097	1.4	>0.05
Fornix tenderness	14	2.21	1.92	0.285	12.90	0.611	0.163	1.47	>0.05

Overall Effect of Therapy In 46 Patients

Table 7: Effect of therapy on Spasmodic Dysmenorrhea

Sr. No.	Result	No. of patients	% age
1.	Completely Cured	05	15
2.	Markedly improved	21	65.60
3.	Moderately improved	06	18.75
4.	Mildly improved	0	0
5.	Unchanged	0	0

Table reveals that maximum number of patients i.e. 65.6% shown marked improvement and 18.75% patients were moderately improved and 15% patients were completely cured, and no patient was unimproved.

Table 8: Effect of therapy on Congestive Dysmenorrhea

Sr. No.	Result	No. of patients	% age
1.	Completely Cured	0	0
2	Markedly improved	0	0
3.	Moderately improved	01	7.14
4.	Mildly improved	03	21.43
5.	Unchanged	10	71.42

The table indicates that 21.43% patients were mildly improved and 7.14% were moderately improved in case of congestive dysmenorrhea.

Marked improvement was observed in the patients suffering from Spasmodic dysmenorrhea but in case of Congestive dysmenorrhea statistically insignificant results were obtained. Therefore, it is concluded that the drug showed significant results in Primary dysmenorrhea not in Congestive dysmenorrhea.

Probable mode of action of Chaturbeeja churna

Chaturbeeja churna has predominantly katu rasa, snigdha guna and ushna virya with vata-hara dosha-karma which pacified the vitiated vata dosha mainly due to ushna virya. Also have garbhashudhikar and shoolhar¹⁴ properties. Due to the garbhashaya shodhaka¹⁵ and sankochaka (ecbolic) action of the Kalajaji it abolishes margavrodha i.e. sanga thus alleviating the vata dosha. Further, the prepared Churna has bitter (Katu) taste, thus having mukhashodhaka and agnivaradhaka properties. So, it increases appetite, digestion and reduces nausea and vomiting. In formulations, component drugs have synergistic and antagonistic actions and net effect is seen in the final formulation.

As mentioned in Charaka, some drugs act by Rasa, some by Virya, some by Guna, some by Vipaka and some act by Prabhava¹⁶. Also, the drug acts by that factor which predominates the others in its composition.

Probable mode of action of Kaishore guggulu

The Probable mode of action of Kaishore guggulu on Kashtartava can be explained as follows –

1. Effect on Dosha: Kaishore guggulu encounters vata, pitta and kapha dosha by virtue of its madhura rasa, kshaya rasa, tikta rasa¹⁷ respectively. Therefore, it acts as tridoshhara. Maximum constituents of drug have madhur vipaka, by virtue of which it is anulomaka thus relieving pratiloma gati of apana vayu thus causing samyaka akunchan prasarana.

2. Effect on Dushya, Agni & Ama: Most of drugs are deepana, pachana, laghu, ruksha, ushna and tikshna. So, they encounter agnimandya & potentiates the weakened dhatwagni and help in amapachana thereby alleviate dushit rasa and artava.

3. Effect on Srotas: Due to amapachana and maargaan Vivrunoti¹⁸ action of katu-rasa, all the involved channels are dilated. So the Srotorodha is removed and rasa- rakta- artavavaha srotovishodhana occurs.

4. Effect on Vyadhi: Many of the drugs are garbhashya sancokhak, rajorodhnashak, shothhar and vedanasthapak by virtue of prabhava which lead to garbhashaya shuddhi and thus helps in easy passage of artava (Menstruation). Also due to *deepan pachan* properties drug has relieving effect on associated features like Aruchi, Malasanga, Chhardi, Hrillas, Bhrama etc. Drugs like Guduchi, Guggulu, Triphala, Sunthi, Pippali and Vidanga are Rasayana¹⁹ (72.73%). So, they work as a Naimittika Rasayana, enhance the nature of relief & stop the recurrences.

In nut shell in Kaishore guggulu maximum ingredients have katu rasa & laghu, ruksha and ushna virya, katu vipaka, vata-kapha shamak, amapachana, dhatu shodhan properties. These properties of formulation help to breakdown the pathogenesis of the disease.

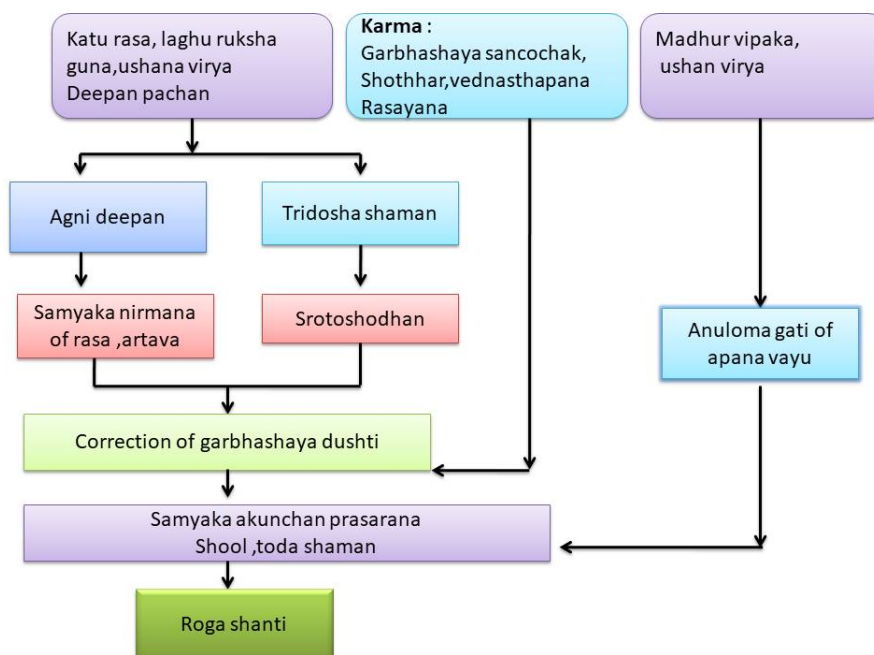


Figure 2: Samprapti Vighatan

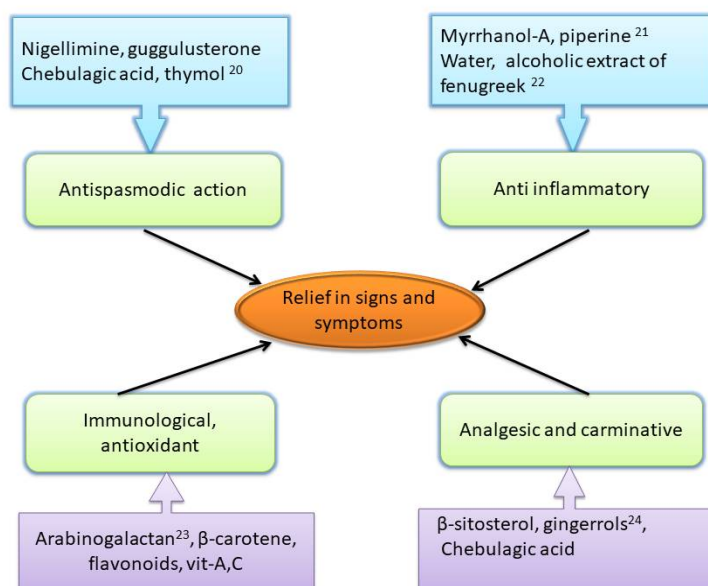


Figure 3: Probable mode of action according to modern pharmacology

With reference to the relevant action of constituents of both drugs, the probable mode of action can be drawn as follows:

The drugs showed significant spasmolytic activity probably mediated through calcium channel blockade. Thus, relieves the pain by direct action on the myometrium. Anti-oxidant activity of the drugs by free-radical scavenging enhances the immunity and general strength of the body. It increases the pain threshold and facilitates better pain tolerance capacity. The drug alters prostaglandin production probably by altering arachidonic acid metabolism. Thus, has anti-inflammatory action and relieves the pain. It inhibits platelet aggregation, thus preventing clot formation. The drugs contain various minerals (Iron, Calcium, Phosphorus etc.) and vitamins (A, B, C) which are also necessary to maintain good health and proper functioning of the body systems. Thus, all these contribute to better health and improved psychology of the patients, allowing them better pain tolerance and even healthier stress-free life.

CONCLUSION

From the present study it can be concluded that 60-70% women suffer from Kashtartava out of which 20-25% remains incapacitated for 1-3 days during each cycle but only 5-8% seek medical advice. Kashtartava can occur in the patient of any age group during her entire reproductive period. Primary dysmenorrhea is mostly found in younger age group (21-30 years) among which students are commonest. Secondary dysmenorrhea is prevalent in the late thirties especially in married and nulliparous females. The drugs Chaturbeej churna and Kaishore guggulu mentioned in Ayurvedic classics relieve Kashtartava by virtue of their Rasapanchaka, Prabhava and Karma. The drugs were well tolerated by the patient. No undue adverse effects were noted in any patient.

Both the drugs showed marked improvement in the intensity, duration and associated symptoms of Spasmodic dysmenorrhoea only whereas no improvement was observed in the Congestive dysmenorrhoea.

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