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Management of *Kashtartava* (Dysmenorrhea) with *Vishwadi Kwatha*: An Open Labelled Single -Arm Clinical Trial

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ABSTRACT

Introduction: *Kashtartava* **(**Dysmenorrhea) is a commonly reported menstrual disorder which affects the working ability and quality of life of the woman. Due to in discreet diet and lifestyle, young women are more liable to get afflicted with this disorder in present era. This trial was planned to evaluate the effect of *Vishwadi Kwatha* which is an unexplored formulation in the management of dysmenorrhoea. **Materials and Methods:** 18 patients fulfilling the inclusion criteria were selected from the OPD of *Prasutitantra* & *Streeroga*, of the institution (3 drop outs). Oral administration of *Vishwadi Kwatha* in a dose of 40ml, twice a day, before meals was given for 1 month. The effect of therapy was assessed by change in the scores of assessment criteria including Visual Analogue Scale. Follow up was done for 1 month. **Result:** Statistically highly significant ($p<0.001$) results were obtained in both the duration (75.60 %) and severity (73.68% relief) of menstrual pain and also in associated symptoms like *Aruchi*(93.75% relief), and *Bala-Bhramsha* (91.17% relief).The mean VAS score of 7.467±1.407 before treatment was reduced to 2.333±0.9 after treatment. **Discussion:** *Vishwadi Kwatha* was mentioned in *Shoola Prakarana* of *Bhaishajyaratnavali* as *Sadya Shoolahara*. The formulation is having *Vatanulomana, Dipana-Pachana, Artavajanana, Kaphahara,* and *Shrotoshodhana* properties which will help the easy expulsion of properly formed *Artava* through the unobstructed channels by correcting the *Vimarga Gati* of *Vayu*. **Conclusion:** Oral administration of *Vishwadi Kwatha* was found to be effective in the management of *Kashtartava* and recommended for further research.

Key words: *Kashtartava, Dysmenorrhea, Vishwadi Kwatha, Menstrual cramps, Shoola*

INTRODUCTION

Dysmenorrhea is a commonly reported menstrual disorder which due to its incapacitating nature affects the working ability and quality of life of the women. It has a detrimental effect on the individual as well as the communities in terms of school and work absenteeism, interference with daily living activities, limitation in socialization and cost of medication and hospitalization.[1] The worldwide prevalence of dysmenorrhoea ranges from 45% to 95% among the females of reproductive age, with 2% to 29% experiencing severe pain.[2,3] A greater prevalence (70% to 90%) is generally reported among younger women (age <24 years).[4] Painful menstruation with associated symptoms like bloating of abdomen, nausea, vomiting, diarrhoea, constipation, tiredness, nervousness etc. can be considered under the terminology *Kashtartava* which needs special medical attention as it degrades the quality of life of women. The main cause of *Kashtartava* is unhealthy and faulty dietary habits, sedentary lifestyle, suppression of natural urges, etc. which lead to obstructions in *Srotas* (bodily channels) and *Vimarga Gamana* (improper movement) of *Apana Vayu* leading to the manifestation of symptoms of *Kashtartava.* In

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conventional medical system, dysmenorrhea is treated by NSAIDs, antispasmodic, analgesics, OCP`s etc. which cannot provide a permanent relief and their long- term use can cause many side effects also. But immediate symptomatic relief is always demanded by the patients especially in case of pain predominant conditions like dysmenorrhoea. Even though *Ayurveda* aims at eliminating the root cause of the diseases through its holistic approach, immediate relief from symptoms is also a matter of concern. The classical reference of the trial drug *Vishwadi Kwatha*[5] which is an unexplored formulation in the field of management of *Kashtartava*, emphasizes that it will provide immediate pain relief (*Sadya Shoolahara*). The ingredient drugs are easily available and cost effective and they are having the properties to correct the pathology of *Kashtartava.* Thus, a clinical trial was planned to evaluate the efficacy of *Vishwadi Kwatha* in the management of *Kashtartava.*

Materials and Methods

Selection of patients:

Patients of age group 12-30 years presenting with signs and symptoms of *Kashtartava* i.e., painful menstruation with or without associated complaints like nausea, vomiting, constipation, breast tenderness, headache, light headedness, anorexia, nervousness etc**.** were screened and enrolled from the OPD of department of Prasuti Tantra and Stree Roga, Murlidhar Ayurved College Hospital, Rajkot. Patients who are the pre-diagnosed cases of pelvic pathologies like uterine fibroid, adenomyosis, ovarian cyst etc, congenital/ acquired anomalies and malignancy of uterus or genital tract, those who are kknown cases of heavy menstrual bleeding, acid peptic disease, peptic ulcer, gastro-esophageal reflux disorder, or any other bleeding disorders were excluded from the study.

Preparation of Drug:

The raw drugs for the preparation of trial drug *Vishwadi Kwatha* were collected from the authentic sources. The pharmacognostical study and pharmaceutical analysis of the trial drug were carried out from the concerned laboratories of B.K.Mody Government Pharmacy college, Rajkot. The raw drugs were made into *Yavakuta* (coarse powder) from the pharmacy of Murlidhar Ayurved College, and subjected to air-tight packing in polythene bags. *Shodhana* (purification) of *Hingu* was done from the department of *Rasashastra* and *Bhaishajya Kalpana* as per the classical reference. The ingredients of *Vishwadi Kwatha*[5] were as per given in table 1.

Table 1: Ingredients of *Vishwadi Kwatha*

Name of the drugs	Latin name	Part used	Total quantity
Eranda	*Ricinus communis*	Root	1 part (≈6.67g)
Shunthi	*Zingiber officinale*	Rhizome	1 part (≈6.67g)
Yava	*Hordeum vulgare* L.	Seed	1 part (≈6.67g)
Hingu (fried in ghee)	*Ferula asafoetida*	Gum resin	2 Rati (250 mg)
Sauvachala Lavana	Black salt	--	2 Rati (250 mg)

Method of preparation of *Vishwadi Kwatha*

Coarse powder (*Yavakuta*) of *Erandamoola*, *Shunthi* and *Yava* in equal quantity (total 20gm) boiled with 16 parts of potable water (320 ml) and reduced to 1/8th part (40ml).[6] It is added with 250 mg of *Hingu* (which is fried with ghee) and 250 mg of *Sauvarchala Lavana* as *Prakshepa*. Patients were advised to prepare the *Kwatha* (decoction) as per the above-mentioned method. Freshly prepared *Kwatha* was advised to be taken in a dose of 40ml twice a day, before food, for 1 month. *Pathya Apathya* (Do's and Don'ts) chart was provided to the patients in local language.

Collection of data:

The study was started after getting the approval from institutional ethics committee (IEC). Informed written consent was taken from each patient before enrolling to the clinical trial. A specially prepared proforma was used to record the data of patients before and after treatment. Effect of therapy was assessed based on the

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scores of visual analogue scale (VAS)[7] for severity of pain before and after treatment as well as the grading of other subjective parameters as per the assessment criteria[8] given in table no. 2

Table 2: Assessment Criteria for Symptoms of *Kashtartava*

Criteria	Grading			
	0	**1**	**2**	**3**
Duration of pain	No pain	Up to 24 hours	Up to 48 hours	Up to 72 hours
Severity of Pain	Menstruation is not painful and daily activity remains unaffected	Menstruation is painful daily activity is not affected no analgesic required.	Menstruation is painful and daily activity affected. Oral analgesics required.	Menstruation is painful and daily activity affected, need to take off from work or school. Oral analgesics not effective need to go to hospital or take injectable
***Aruchi* (Anorexia)**	Absent	Loss of appetite without alteration in eating habits.	Oral intake decreased without significant weight loss, dehydration or malnutrition	Inadequate oral caloric or fluid intake, tube feeding, TPN or hospitalization indicated
***Chardi* (Vomiting)**	Absent	1 episode/24 hours, Intervention not indicated	2-5 episodes/ 24-hour, Outpatient IV hydration, medical intervention needed	>5 episodes/ 24 hr. Tube feeding, TPN or hospitalization indicated.
***Vibandha* (Constipation)**	No constipation, occasional or intermittent symptoms.	Frequency once in a day with passage of very hard stool	Bowel evacuation on 2 -3 days, regular laxative or enema not useful	Obstipation with manual evacuation indicated.
***Bala-Bhramsha* (Fatigue)**	No fatigue	Relieved by Rest	Fatigue not relieved by rest, limiting instrumental activities of daily living	Fatigue not relieved by rest, limiting self- care and activities of daily living
***Shira Shula* (Head ache)**	No headache	Mild pain persists for less than 6 hours.	Moderate pain limiting instrumental ADL*	Severe pain, limiting selfcare ADL.
***Bhrama* (Dizziness)**	No dizziness	Mild unsteadiness or sensation of movement, 1-2 times during menstrual period	Moderate unsteadiness or sensation of movement, limiting instrumental ADL.	Severe unsteadiness or sensation of movement, limiting instrumental ADL
***Pindikodveshtana* (Calf muscle cramps)**	No cramps	Mild pain persists for less than 6 hours.	Moderate pain limiting instrumental ADL	Severe pain, limiting selfcare ADL

*ADL- Activities of Daily Life.

The data of total 15 patients who had completed the treatment protocol along with follow up were considered for analysis of effect of therapy.

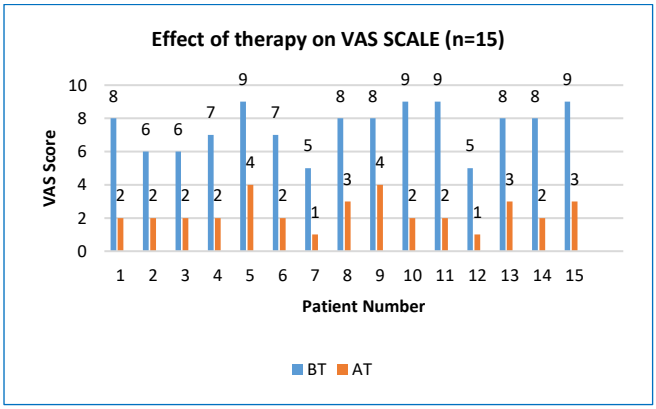
ISSN: 2456-3110 ORIGINAL ARTICLE November 2024

RESULTS

Effect of therapy on pain as per VAS (Visual Analogue Scale) Scores:

The mean VAS score was 7.467±1.407 before treatment and it was reduced to 2.333±0.9 after treatment. The distribution of VAS Score among 15 patients, before and after treatment is shown in the graph no:1

Graph 1: VAS Score (before and after treatment)



Highly significant difference($p<0.001$) was observed in VAS Score of severity of pain before and after treatment as shown in table no:3.

Table 3: Effect of therapy on VAS Scores

Mean ± SD		Mean Difference	t	P	Significance
BT	AT				
7.467 ± 1.407	2.333±0.900	5.133±1.060	18.754	<0.001	HS

*HS: Highly Significant

The percentage of relief in different symptoms of *Kashtartava* is given in table no. 4.

Table 4: Effect of therapy on chief complaints and associated complaints (n=15)

N*	Assessment Criteria	Mean Score		Mean Difference	Percentage of Relief
		BT	AT		
15	Duration of pain	2.73	0.67	2.06	75.60 %
15	Severity of pain	2.53	0.67	1.86	73.68%
11	*Aruchi*	1.06	0.06	1	93.75 %
6	*Chardi*	0.733	0.2	0.53	72.72%
9	*Vibandha*	0.66	0.13	0.53	80%
14	*Bala-bhramsh*	2.26	0.2	2.06	91.17%
8	*Shirashoola*	1	0.13	0.86	86.67%
4	*Bhrama*	0.4	0	0.4	100%
8	*Pindikodweshtana*	1.067	0.2	0.86	81.25%

*N= Number of patients presenting with the symptom

Wilcoxon Signed Rank test was applied to find out the significance of difference between the scores given to the symptoms before treatment (BT) and after treatment (AT) as per the assessment criteria. Statistically highly significant ($p<0.001$) differences between the scores were obtained in duration of pain, severity of pain, *Aruchi*, and *Bala-Bhramsha*. Significant ($p<0.05$) results were obtained in *Chardi, Shirashoola* and *Pindikodweshtana*. The difference was insignificant in the scores of *Vibandha* and *Bhrama.*

DISCUSSION

Ayurvedic approach towards dysmenorrhea differs from the conventional medical approach which target only pain by controlling prostaglandin synthesis through nonsteroidal anti-inflammatory drugs or by suppression of ovarian function through oral contraceptives. *Ayurveda* addresses the subtle and holistic mechanisms of digestion, metabolism, formation of the menstrual blood and the process of its expulsion which all are inter-connected. The alteration in any phase of these can create an inflammatory environment in which pain can be manifested as a main symptom leading to *Kashtartava.* Thus, the first focus of *Ayurvedic* management of *Kashtartava* is to correct *Agni* (digestive fire) and prevent the formation of *Ama*. This can lead to formation of "*Shuddha Artava*" which is easy to be expelled. Samprapti(etiopathogenesis) of *Kashtartava* mainly depends on the vitiation of *Vata Dosha* with or without the involvement of vitiated *Kapha Dosha*. The line of treatment should be *Dipana-Pachana* (digestive), *Artavajanana* (promoting the production of *Artava*), *Kaphahara* (alleviating *Kapha*), *Shrotoshodhana* (clearing the channels) and *Vatanulomana* (correction of the direction/function of

ISSN: 2456-3110 ORIGINAL ARTICLE November 2024

Vata) which will help the easy expulsion of properly formed *Artava* through the unobstructed channels by the coordinated activity of *Vayu.* The main causative factors for vitiation of *Vata* are directly involved in the pathogenesis of *Kashtartava*. In this study, excessive use of *Katu and Madhura Rasa,* faulty dietary habits like *Samashana* (mixing the wholesome and unwholesome foods), improper sleep, lack of *Vyayama* (exercise) and *Vata- Pitta Prakruti* (physical constitution) were identified as the main risk factors for development of *Kashtartava*. Excessive use of *Katu Rasa* may be leading to *Vata- Pitta Prakopa* and excessive use of *Madhura Rasa* may be leading to *Kapha Prakopa* leading to the *Avarana Samprapti* of *Kashtartava.* A previous research on *Kashtartava* also reported the lack of *Vyayama* (physical exercise) in majority (74.19 %) of patients.[9] Another research study[10] on *Kashtartava* had reported that majority (66.6%)of the patients were having *Vata -Pitta Prakriti* which is similar to the findings of the present study. The commonest associated complaint was found to be *Bala-Bhramsha* (unusual tiredness) which was reported by 94.44% of the patients. 77.77% of patients reported *Aruchi* (anorexia) as an associated complaint.61.11% were having *Pindikodweshtana* (calf muscle cramps), 50% were having *Vibandha* (constipated bowel) during menstrual period. 44.44% of patients reported *Shirashoola* (head ache) and *Chardi* (vomiting) as associated complaints. 22.22% of patients were complaining of *Bhrama* (giddiness) during menstrual period. In one of the previous studies, the commonest associated complaint was found to be nausea (58.3%) and also 35% patients reported *Aruchi* (anorexia)[10] Another study also reported nausea (33.1%,) as the commonest associated complaint followed by vomiting (21.2%).[11] These indicate the prominent role of *Kapha Dosha* in the *Samprapti* of *Kashtartava* along with the *Vata Dosha.*

Probable mode of action of *Vishwadi Kwatha* in *Kashtartava*

Majority of the ingredient drugs of *Vishwadi Kwatha* are having *Ushna Veerya* (hot potency) and predominant *Rasa* (lingual tastes) are *Katu* (pungent), *Kashaya* (astringent) and *Madhura* (sweet). *Eranda* and *Shunthi* are having *Madhura Vipaka* and the rest of the drugs including *Prakshepa Dravya* are having *Katu Vipaka. Eranda, Hingu* and *Sauvarchala Lavana* are having *Snigdha Guna* while *Shunthi* and *Yava* are *Rooksha*. Thus, the ingredients of *Vishwadi Kwatha* as well as, the formulation are mainly having *Vata-Kapha Pradhana Tridoshahara* action in the body. *Shunthi* is having the properties like *Deepana, Rochana, Vrushya, Vibandhanut, Shophahara* etc. which are helpful in breaking the *Samprapti* of *Kashtartava.* It has been widely used in gynaecological disorders. Various components of ginger like Gingerol, Shogaol, Paradol, Zingerones, and Gingerdione have anti-inflammatory pharmacological actions and act as a potent inhibitor of cyclooxygenase (COX-2), resulting in the inhibition of prostaglandins and leukotriene biosynthesis.[12] A systematic review published in 2022, on effectiveness of ginger compared with non-steroidal anti-inflammatory drugs (NSAIDs), suggested that the usage of ginger up to two grams per day in divided doses of powder or dietary form for three days from the first day of the menstrual cycle is safe and effective for primary dysmenorrhoea.[13] Ginger has been shown to share pharmacological properties with NSAIDs and recommended as it suppresses PG synthesis through the inhibition of cycloxygenase-1 and Cox 2 and has fewer side effects than NSAIDs.[14] Ginger is also found to be as effective as mefenamic acid on pain relief in primary dysmenorrhea and recommended as an alternative treatment for primary dysmenorrhea.[15] *Eranda Moola* is considered as the best drug for pacifying *Vata* and having a targeted action at the site of *Apana Vayu* i.e., *Pakwashaya, Kati, Shroni, Vasti, Garbhashaya* etc. It is especially indicated in diseases like *Udavarata, Gulma, Anaha, Vasti-Shoola, Kati Shoola* etc. So, it is having the prime role in *Anulomana* of *Apana Vayu* which helps in easy expulsion of menstrual blood in case of *Kashtartava.* Different clinical studies using *Erandamoola Kwatha* (decoction), *Erandamoola Arka* (distilled formulation) etc. have proven its efficacy in the management of primary dysmenorrhoea. [16,17] *Yava* is especially recommended in the diet as part of *Rajaswala Paricharya* for improving menstrual health and prevention of

ISSN: 2456-3110 ORIGINAL ARTICLE November 2024

menstrual disorders. It is considered as *Pathya* (wholesome diet) for all kinds of *Yoni Vyapad* (gynaecological disorders). *Laghu-Ruksha* and *Lekhana* properties are helpful in removing excessive *Kleda* (accumulation of liquid waste) from the body which facilitate the process of expulsion of menstrual fluid and its *Madhura rasa* and *Sheeta Veerya* can contribute in increasing *Dhatubala* (strength of structural component of the body).[18] *Hingu* is having the properties like *Deepana, Rochana, Chedana,* and *Anulomana.* It is especially indicated in diseases like *Shoola, Adhmana, Gulma* etc. which are related to the features of *Kashtartava.* Recent research studies indicate the effectiveness of *Shodhita Hindu* in the management of primary dysmenorrhoea.[19] The chemical compounds like Azulene, ferulic acid, luteolin and umbelliferones present in *Hingu* were found to be responsible for its anti-spasmodic and anti-prostaglandin activity.[20] The anti-inflammatory, analgesic and antispasmodic effects in asafoetida suggests a NSAID-like mechanism and a randomized comparative trial showed significant pain reduction on day one compared with mefenamic acid and suggested as an alternative for it in cases of primary dysmenorrhea.[21] *Sauvarchala Lavana* is especially *Deepana-Pachana, Rochana* and *Vatanulomana* in nature. Thus, the prominent *Katu Rasa* of the formulation may act on the *Jatharagni level* as *Deepana-Pachana* and prevent the formation of *Ama* which leads to the proper formation of *Artava. Teekshna Guna* of *Eranda*, *Shunthi* and *Hingu* may help to penetrate the *Srotas* and *Lekhana* property of *Yava* remove the *Sanga* (obstructions) in *Srotas* which facilitates the expulsion of *Artava* (menstrual blood). The *Vatanulomana* property of the drugs leads to the correction of *Vimarga Gati* of *Vayu*. All these ultimately results in relieving the symptoms of *Kashtartava* by promoting easy expulsion of menstrual blood.

Conclusion

Kashtartava can be considered as a symptom-complex with the pathological origin of *Agnidushti* and formation of *Ama* leading to *Sanga* in *Srotas* resulting in impaired function (*Vimarga Gamana*) of *Vata.* The line of treatment for *Kashtartava* should be *Dipana-Pachana, Artavajanana, Kaphahara, Shrotoshodhana* and *Vatanulomana* along with *Nidanaparivarjana*. Drugs having the properties like *Shoolaprashamana* and *Vedanasthapana* are useful in the management of *Kashtartava.* The protocol of oral administration of *Vishwadi Kwatha* in a dose of 40ml twice a day, before food, for a duration of 1 month was found to be safe and effective in the management of *Kashtartava* and it is recommended for further multi-center trials with large sample size.

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ISSN: 2456-3110 **ORIGINAL ARTICLE** November 2024

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