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Research Article

# A CLINICAL STUDY TO EVALUATE EFFICACY OF *TRIVRITADI TAILA ANUVASANA BASTI* IN THE MANAGEMENT OF *KASHTARTAVA* WITH SPECIAL REFERENCE TO PRIMARY DYSMENORRHEA

**Renu[1]*, B.Pushpalatha[2], K.Bharathi[3], Devendra Singh[4]**

*[1]P.G.Scholar, [2]Associate Professor, [3]Professor and HOD, Department of Prasuti-Stri Roga, NIA, Jaipur.
[4]P.G. Scholar, Department of Roga Nidana evam Vikriti Vigyana, NIA, Jaipur, India.

**KEYWORDS:** Dysmenorrhea, *Kashtartava, Vatadosha, Trivritadi Taila Anuvasana Basti.*

***Address for correspondence**
**Dr. Renu**
P. G. Scholar,
Department of Prasuti-Stri Roga,
NIA, Jaipur.
Email: renufarak@gmail.com
Contact: 7597802632

## ABSTRACT

Dysmenorrhea is the most common gynecological problem faced by women during their adolescence and also in reproductive age which causes significant discomfort and anxiety for the women. In modern medicine dysmenorrhea is treated by oral contraceptive pills, non-steroidal anti-inflammatory drugs, antispasmodic, analgesics etc. This treatment may relieve symptoms of dysmenorrhoea but it does not address the root of the problem. Long term use of these causes side effects. So to minimize these complications, an attempt is made to find out safe, potent, cost effective remedy from Ayurveda for the management of *Kashtartava.* In Ayurveda *Kashtartava*, term which is being used for the condition where in a women may suffer with pain during menstruation. Pain is the main feature of *Kashtartava*, so it has strong relation with *Vata Dosha*. For the management of this vitiated *Vata*, treatment that effect direct on the place of *Vata* should be selected therefore by administering *Basti* to normalize vitiation of *Vata* and proper measures to correct the *Agnivikara* should be the prime objectives of the treatment. Keeping this point in view, the present clinical trial, a clinical study to evaluate efficacy of "*Trivritadi Taila Anuvasan-Basti*" in the management of *Kashtartava* with special reference to Primary Dysmenorrhea was taken. *Trivritadi Taila Anuvasan-Basti* due to the properties of *Anulomana* and *Vatahara* may it effectively brings down the *Pratiloma Gati Vata* which is mentioned in *A.S.Utt.* 39/29 for *Udavartini Yonivyapad,* which is one of the main disease conditions compares with *Kashtartava* (Primary dysmenorrhoea). Results were assessed on the basis of improvement in the subjective parameters. The study reveals that patients of *Kashtartava* after treatment showed significant improvement in chief complaints, from the above trial it is clear that *Trivritadi Taila Anuvasan-Basti* can be used as a safe and effective therapeutic agent in the management of *Kashtartava*.

## INTRODUCTION

Dysmenorrhea is critical global health issue in reproductive age women, as it causes frequent short-term work and school absenteeism and has a significantly negative effect on daily activities.[1] Dysmenorrhoea is defined as painful menstruation so as to incapacitate day to day activities.[2] Primary dysmenorrhea is extremely common, especially among adolescents. Primary dysmenorrhea refers to menstrual pain without pelvic pathology.[3] The prevalence of primary dysmenorrhea was 85.4% of these, 28.5% had mild, 38.1% moderate and 18.8% severe dysmenorrhea pain.[4] In Ayurveda, *Kashtartava* is a broad term which covers all problem and ailments that a woman may suffer during or around menstruation. It includes both primary and secondary types of dysmenorrhea. For the present study, only primary dysmenorrhoea is taken with *Kashtartava* to exclude the pathological

cases, but, in fact, no disease can be primary according to Ayurvedic principles, as each and every disease has its certain pathogenesis. Still it makes the study easier and the data can be analyzed easily, if a single type origination of disease is taken under consideration. *Acharya Charaka* has mentioned that *Yoniroga* can't occur without vitiation of *Vata.* As *Vata* is main causative factor it should be treated first. [5] According to Ayurveda, pain is an indication of *Vata Vikriti* – *Vaatadrite Nasti Ruja.*[6] Pain is the main feature of *Kashtartava*, so it has strong relation with *Vata Dosha*. According to *Acharya Sushruta, Apana Vayu* and *Vyana Vayu* are mainly responsible for *Artava Utpatti.*[7] Normal menstruation is the function of the *Apanavata.*[8] For the production of *Artava*, *Apana* and *Vyana* work in coordination with each others. *Vyana Vayu* has control over the muscles which brings about actions such as contraction, relaxation, extension, flexion etc. Contraction, relaxation of the uterus and its related organs is the function of *Vyana Vayu*, after which *Artava* is expelled out by *Anulomana kriya* of *Apana Vayu*. If women have any difficulty in menstruation it indicates *Apana and Vyana Vatadushti*. So *Kashtartava* is considered as a *Tridoshaja Vyadhi* with *Vata* predominance especially due to derangement of *Apana* and *Vyana Vata. Basti* has being mentioned as one of the best therapeutic procedure for alleviation of vitiated *Vata.*[9] Out of all *Sthanas* of *Vata* the *Pakvadhan* is dominant and *Basti* can be considered as the closest path to reach *Pakvashaya* than other treatment procedures. *Matra Basti* is a type of *Anuvasana Basti* and the simplest type of *Basti*. So it is selected for the present study due to its indication in any season, at any age, without much restriction. [10] In addition *Agnivikara* induces vitiation of *Apana Vata* since the three *Vayus- Prana, Apana* and *Samana*, located normally in their respective places initiate and preserve the metabolic power of the body. [11] The selected drug is *Vatashamaka* and correct the *Agnivikara* mentioned by the classics and *Trivritadi Taila Anuvasan-Basti* due to the properties of *Anulomana* and *Vatahara* may it effectively brings down the *Pratiloma Gati Vata* which is mentioned in *A.S.Utt.* 39/29[12] for *Udavartini Yonivyapad* which is one of the main diseases conditions compares with *Kashtartava* (Primary dysmenorrhoea).

**Drug used for Present Study**

For the present study "*Trivritadi Taila Anuvasana Basti*" was used. The formulation was prepared by NIA, Jaipur pharmacy according to classical textual mode of preparation of oil.

**AIM AND OBJECTIVES**

1. To study etiopathogenesis of *Kashtartava* as per the classical and modern literature.
2. To evaluate the therapeutic efficacy of *Trivritadi Taila Anuvasana Basti* in the management of *Kashtartava*.

**MATERIALS AND METHODS**

**Design of the study**

The method adopted in present study is Randomized, Clinical, Open study.

1. Study type: Interventional
2. Masking: Open label
3. Purpose: Treatment
4. Timing: 2 consecutive cycles.
5. End point: Efficacy
6. Subjects: Minimum of 15 patients

**Selection of cases:** Total 16 clinically diagnosed and confirmed cases of Primary Dysmenorrhoea were registered for the present clinical trial

**Source of data:** The cases were selected from the O.P.D. / I.P.D. of P.G. Department of *Prasuti-Striroga*, National Institute of Ayurveda (N.I.A.) Hospital, Jaipur.

**Criteria for selection of patients**

**Inclusion criteria**

- Patients coming with chief complaint of *Kashtartava* with scanty or average amount of menses along with associated symptoms.
- Patients in age group of 16 to 30 years.
- Patients with H/O using analgesics during menses.

**Exclusion criteria**

- The patient suffering from malignant systemic disorders, specially those are mentioned as *Asadhya vyadhi* as per clinical text of Ayurveda will be excluded.
- Subjects having organic pathology of uterus and adnexa eg.-Fibroid uterus, carcinoma of endometrium etc.

**Criteria for withdrawal**

- If any serious condition develops during the course of trial which requires urgent treatment.
- If the patient wants to withdraw from clinical trial by herself.
- Patient with irregular follow up and non-compliance.

**Investigation:** Laboratory test of blood, urine and USG were carried out before treatment to rule out any other pathological conditions.

**Method of Data Collection**

- The method adopted in present study is clinical, open study with a pre-test & post-test design.
- 16 patients are selected for the trial, were *Trivritadi Taila Anuvasan- Basti* (*Matra-Basti*), administered per rectum 60ml/day for 7 alternate days, *Basti* started 14 days before onset of expected menstrual cycle and same process done in next consecutive menstrual cycles. 01 patient discontinued and 15 patients were completed the trial.
- **Duration for clinical trial:** The trial will be carried out for 60 days in two consecutive menstrual cycles. The assessment was done after each cycle on 5$^{th}$ day of cycle and follow-up for the one next menstrual cycle.
- **Criteria of assessment:** A special scoring pattern was applied in symptoms and associated complaints.
- **Follow up study:** Clinical assessment will be done after completion of 2 consecutive menstrual cycles.
- The parameters of signs and symptoms were scored on the basis of standard method of statistical analysis.

**Method of Administration of *Matra Basti***

The patient was asked to take light meal, neither too *Snigdha* nor too *Ruksha* and not more than 3/4$^{th}$ of the usual quantity. The patient was advised to take left lateral position with left lower extremity straight and right lower extremity flexed on knee and hip joint. The patient was asked to keep his left hand below the head. 60ml of lukewarm *Taila* was taken in enema syringe. Rubber catheter oleated with *Taila* was attached to enema syringe. After removing the air from enema syringe, rubber catheter was administered into the anus of the patient up to the length of 4 inches. The patient was asked to take deep breath while introducing the catheter and drug.

**Criteria of assessment**

The improvement in the patient 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 it severity and duration of persist. Other associated symptoms according to Ayurveda as well as per modern, also assessed by the scoring method.

**Assessment of Pain (Dysmenorrhoea):** A special Scoring Pattern was applied in symptoms:

| **Pain Intensity** | Grade |
|---|---|
| Absent | 0 |
| Mild (pain do not interfere with daily activity) | 1 |
| Moderate(daily activity hampers, relieves with analgesics) | 2 |
| Severe (do not relieved by analgesics) | 3 |

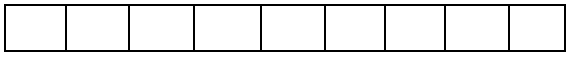
| **Duration of Pain** | Grade |
|---|---|
| Absent | 0 |
| Pain for one day (for few hours) | 1 |
| Pain for one day(for whole day) | 2 |
| Pain for>or=2 days | 3 |

| **Nature of Pain** | Grade |
|---|---|
| Absent | 0 |
| Occasional | 1 |
| Dull | 2 |
| Spasmodic | 3 |

| **Menstrual Flow Duration** | Grade |
|---|---|
| 1 day | 3 |
| < or =2 days | 2 |
| 3-4 days | 1 |
| > or =5 days | 0 |

| **Menstrual Flow Amount** | Grade |
|---|---|
| Scanty (spotting) | 3 |
| Average (1-2 pads) | 2 |
| Normal (3-4 pads) | 1 |
| Excessive (5 pads or more) | 0 |

**Visual Analog Scale**



**0 1 2 3 4 5 6 7 8 9**

**And further it is assessed as follows**

| | | |
|---|---|---|
| 7 - 10 | severe pain | Grade 3 |
| 6 - 4 | moderate pain | Grade 2 |
| 1 - 3 | mild pain | Grade 1 |
| 0 | no pain | Grade 0 |

**Rating scale for the assessment of improvement in the symptoms after therapy**

**Percentage of relief effect**

| | |
|---|---|
| Mild Relief | (0 to 25%) relief in the signs and symtoms |
| Moderate relief | (>25 to 50%) relief in the signs and symtoms |
| Significant Relief | (>50 to 75%) relief in the signsand symtoms |
| Excellent Relief | (>75%) relief in the signs and symtoms |

**OBSERVATIONS**

Total 15 patients included in trial in which 33.33% of the patients were in the age group of 16-20yrs, 33.33% of the patients in age 21-25yrs and also 33.33% of the patients in age 26-30yrs. Most i.e. 66.67% of the patients included in trial were belongs to Hindu religion, 60% patients were housewives, 53.33% of the patients were married, 73.33% of the patients were from lower middle class. Pertaining to personal history it is fond that; 66.67% of the patients with the habit of vegetarian diet, 86.67% of the patients addicted to tea, 80% of the patients with normal sleep and 80% of the patients with constipated bowel habit, 66.67% of the patients had *Mandagni*, 66.67% of the patients had *Krurakostha*. From menstrual history it is about that, 53.33% of the patient's menarche onset was in the age of 14yrs, 66.67% of the patients had regular menstruation, 80% of the patients had moderate amount of menstrual blood loss, 70% patients were having 3-4 days of duration of menses, 53.33% of the patients were having 28-30 days of interval of menstrual cycle. From pain wise history, it is observed that, in 60% patients pain was at lower abdomen, lower backache and radiating to thigh, 53.33% of the of patients having spasmodic type of pain and 60% of the patients having duration of pain for = or >2 days.

**RESULTS**

**Table 1: Shows the pattern of clinical recovery in Subjective Parameters in 15 patients**

| S. No. | Symptoms | Mean | | Dif. | % of Change | SD | SE | P | Result |
|---|---|---|---|---|---|---|---|---|---|
| | | BT | AT | | | | | | |
| 1. | Pain Intensity | 2.267 | 0.867 | 1.400 | 61.75% | 0.507 | 0.130 | <0.0001 | E.S. |
| 2. | Pain Duration | 2.600 | 0.933 | 1.667 | 64.11% | 0.723 | 0.186 | < 0.0001 | E.S. |
| 3. | Nature of Pain | 2.333 | 1.067 | 1.267 | 54.30% | 0.457 | 0.118 | <0.0001 | E.S. |
| 4. | Flow Duration | 1.000 | 0.8667 | 0.133 | 13.33% | 0.516 | 0.133 | 0.9999 | N.S. |
| 5. | Flow Amount | 1.933 | 1.467 | 0.467 | 24.16% | 0.516 | 0.133 | 0.0156 | S. |
| 6. | Associated Symptoms | 2.000 | 0.0.467 | 1.533 | 76.65% | 0.516 | 0.133 | <0.0001 | E.S. |
| 7. | VAS Scale | 2.267 | 1.200 | 1.067 | 47.07% | 0.593 | 0.153 | 0.0002 | E.S. |
| 8. | Wong Backer facial grimace scale | 2.267 | 1.067 | 1.200 | 52.39% | 0.560 | 0.144 | 0.0001 | E.S. |

**E.S. = Extremely Significant, S. = Significant, N.S. = Non Significant**

Extremely significant results are shown on Pain Intensity, Pain Duration, Nature of Pain, Associated symptoms, VAS Scale and Wong Baker facial grimace scale. Results on Flow Amount found significant and non-significant result found on Flow Duration.

**Table 2: Shows the pattern of clinical recovery in various Associated Symptoms in 15 patients**

| S.No | Symptoms | Mean | | Dif. | % of Relief | SD | SE | P | Results |
|---|---|---|---|---|---|---|---|---|---|
| | | BT | AT | | | | | | |
| 1. | Nausea | 0.800 | 0.067 | 0.733 | 91.66% | 0.457 | 0.118 | 0.0010 | E.S. |
| 2. | Vomiting | 0.600 | 0.067 | 0.533 | 88.88% | 0.516 | 0.133 | 0.0078 | V.S |
| 3. | Fatigue | 0.800 | 0.067 | 0.733 | 91.66% | 0.457 | 0.118 | 0.0010 | E.S. |
| 4. | Headache | 0.600 | 0.133 | 0.466 | 77.78% | 0.516 | 0.133 | 0.0156 | S. |
| 5. | Fainting | 0.133 | 0.067 | 0.067 | 50.03% | 0.258 | 0.067 | > 0.999 | N.S. |
| 6. | Sweat | 0.333 | 0.133 | 0.200 | 60.00% | 0.414 | 0.107 | 0.2500 | N.S. |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 7. | Diarrhoea | 0.133 | 0.067 | 0.067 | 50.03% | 0.258 | 0.067 | > 0.999 | N.S. |
| 8. | Constipation | 0.800 | 0.067 | 0.733 | 91.66% | 0.447 | 0.118 | 0.0010 | E.S. |
| 9. | Vaginal Discharge | 0.800 | 0.200 | 0.600 | 75.00% | 0.507 | 0.130 | 0.0039 | V.S. |
| 10. | Breast Tenderness | 0.533 | 0.133 | 0.400 | 75.00% | 0.507 | 0.130 | 0.0313 | S. |

**E.S. = Extremely Significant, V.S. = Very Significant, S. = Significant, N.S. = Non Significant**

Extremely significant results are shown on Nausea, Fatigue and Constipation. Very significant results obtained on Vomiting and Vaginal discharge. Significant results are shown on Headache and Breast tenderness. Results on Fainting, Sweat and Diarrhoea were found Non-significant.

**Table 3: Shows the % improvement of symptoms**

| S.No. | Cardinal Symptoms | Result (%) |
|---|---|---|
| 1 | Nausea | 91.66% |
| 2 | Vomiting | 88.88% |
| 3 | Fatigue | 91.66% |
| 4 | Headache | 77.78% |
| 5 | Fainting | 50.03% |
| 6 | Sweat | 60.00% |
| 7 | Diarrhoea | 50.03% |
| 8 | Constipation | 91.66% |
| 9 | Vaginal Discharge | 75.00% |
| 10 | Breast Tenderness | 75.00% |
| 11 | Pain Intensity | 61.75% |
| 12 | Pain Duration | 64.11% |
| 13 | Nature of Pain | 54.30% |
| 14 | Flow Duration | 13.33% |
| 15 | Flow Amount | 24.16% |
| 16 | Associated Symptoms | 76.65% |
| 17 | VAS Scale | 47.07% |
| 18 | Wong Baker Facial Grimace Sale | 52.93% |
| | **Average % of relief** | **63.67**% |

**Table 4: Overall Effect of Therapy**

| S. No. | Effect of therapy | Result | Patients | |
|---|---|---|---|---|
| | | | No. | % |
| 1 | Mild | (0 to 25%) | 00 | 0.00% |
| 2 | Moderate | (>25 to 50%) | 02 | 13.33% |
| 3 | Significant | (>50 to 75%) | 08 | 53.33% |
| 4 | Excellent | (>75%) | 05 | 33.33% |

## DISCUSSION

### Mode of action of *Trivritadi Taila*

***Trivrita:*** *Katu, Teekshana* and *Ushana* properties lead to *Deepana* and *Amapachana* and than *Sroto Shodhana* while *Virechana* effect leads to clearance of *Margavarodha* and *Pakvashaya*. Thus *Apana-vaigunya* is corrected. Anti-inflammatory activity helps in pacifying the pain in dysmenorrhoea. *Trivirita* is *Sukhavirechaka* and pacifies *Kapha* and *Pitta Dosha*, hence it manages *Apanavaigunya* by removing obstruction caused by *Pitta* and *Kapha* i.e. breaks the *Margavrodha* type of pathogenesis as explained in *Udavartini Yonivyapada.*

***Dashamoola*:** *Dashmoola* as the name suggests contains roots of ten different plants. Of these, five are known as *Brihat panchmoola* and the remaining as *Laghu panchmoola*. *Acharya Charaka* has used the term *Dashamoola* at various places but the drugs of *Dashamoola* have been depicted in *Shothahara Dashemani*[13] and *Pancha-Pancha-moola.*[14] *Acharya Sushruta*[15] coined the very term for the first time which includes *Laghu* and *Brihat panchmoola*.

**Qualities and uses of *Dashamoola:*** *Acharya Charaka* has appraised the *Dashamoola* as *Shothahara* (the one which is either anti-inflammatory and reduce oedema), while *Acharya Sushruta* has apprised these as *Kaphapittaanila-hara*, *Shwasahara, Aampachaka* and *Sarvajava-rahara.*[16]

***Tila Taila*:** *Tila Taila* has all the qualities that are opposite to *Vata Dosha* e.g. it is *Guru, Snigdha*, *Madhura* and *Ushna*. Its *Ushana Virya* results in *Amapachana* hence treat the obstructed channels while rest of the properties enables it to act as *Dhatuposhaka*. *Taila* is also regarded as the best *Vata* pacifier. All these qualities of *Tila Taila* are also regarded as the best *Vata* pacifier. All these qualities of *Tila* enable it to regulate the vitiated *Vata* when its obstruction is removed by the *Trivrita* ingredient. *Taila* carries the whole potency of drug in it. *Taila* (Lipid soluble) travels directly through the cell membrane (passive diffusion) because of homogeneity between the drug and cell membrane. The cell membrane provides free entry of the drug. Further the mild temperature of oil at the time of administration enhances its diffusion.

**Mode of action of *Matra Basti* on *Kashtartava***

*Matra Basti* has both local and systemic effects. It causes *Vatanulomana* thereby normalizing *Apana Vata*. Mode of action of *Matra Basti* is defined in Ayurvedic classics very well. *Acharya* have explained its mode of action on Ayurvedic principles of *Dosha* and *Dosha-Dushya Sammurchhana*. *Acharya Sushruta*[17] says that the *Virya* of *Basti* administered through the *Basti* reaches the whole body through the channels (*Srotas*) as the active principles in the water when poured at the root of the tree reaches the whole plant. This definition explains how *Basti* acts on whole the body after reaching in the gastro-intestinal tract. Spasm caused by vitiated *Apana* and *Vyana Vayu* causing obstruction to the flow of menstrual blood is the general underlying pathology. *Tail* enters to the *Srotus* and removes the *Sankochana* (Spasm) by virtue of its *Snigdha Sukshama Vyavayi* and *Vikashi* etc., fast spreading nature. *Basti Dravya* normalizes the function of *Vata* by pacifying it after reaching all over the body. Its contents act through their different chemical constituents to restore the normal menstrual physiology and thus, relieve pain during menstruation.

*Basti* can be affect on *Kashtartava* by following mechanisms; improves overall nutrition status of body, improves intestinal health and absorption, nourishing the system, increasing the immunity by detoxifying the system, and by action of active principle of drug it breaks the pathology. Thus, *Basti* will act not only the pain, but the entire whole the clinical picture of *Kashtartava* (physical & mental symptoms) of body by normalizing the functions of *Vata*.

## CONCLUSION

1. *Trivritadi Taila Anuvasan Basti* per rectally act as *Shodhana* therapy effective in relieving *Kashtartava*. The effect of *Trivritadi Taila Anuvasana Basti* had prolonged effect in relieving cardinal and associated symptoms. Further it helps to reduce the possibility of recurrence which was evident on follow-up.
2. The symptomatic improvement was found that average percentage of relief i.e. 63.67%.
3. 05 (33.33%) patient showed excellent relief, 08 (53.33%) patients showed significant relief, 02 (13.33%) patients showed moderate relief and no any patient found with mild relief.
4. Therapeutic effect of "*Trivritadi Taila Anuvasan Basti"*- showed relief by improvement with 61.75% in pain intensity, 64.11% in pain duration, 54.30% in nature of pain,13.33% in menstrual flow duration, 24.16% in menstrual flow amount, 76.65% in associated symptoms, 47.07% in VAS scale and 52.39% in Wong Baker facial grimace scale.
5. Results prove that "*Trivritadi Taila Anuvasan Basti"* proved to be an effective & dependable remedy in the management of *Kashtartava.*
6. Patients taken the "*Trivritadi Taila Anuvasan Basti"* very well with no complaints of any side effect or toxic effects.

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