RESEARCH PAPER

CLINICAL EFFICACY OF AYURVEDIC TREATMENT REGIMEN IN THE MANAGEMENT OF KASHTARTAVA (PRIMARY DYSMENORRHEA) – A RANDOMIZED CONTROLLED CLINICAL TRIAL

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Abstract

Background: Dysmenorrhoea refers to the pain associated with menstruation, typically occurring in the lower abdomen or pelvis. The intensity of pain can vary from mild to severe, and in some cases, the discomfort is debilitating enough to interfere with daily activities, including work and school attendance. Kashtartava (painful menstruation/primary dysmenorrhea) in Ayurvedic terms is characterized by painful menstrual cramps and is often associated with Vata dosha (bio-energetic force responsible for movement) imbalance.

Objective: To evaluate the clinical efficacy and safety of Kuberaksha Vati combined with Dashmoola Taila Matra Basti (medicated oil enema) in managing primary dysmenorrhea compared with conventional pharmacotherapy.

Methods: A prospective, randomized, open-label, double-arm clinical trial was conducted at XXXXXX. A total of 205 patients aged 15–24 years with primary dysmenorrhea were enrolled. Group A (102 patients) received Kuberaksha Vati (1 g three times daily) and Dashmoola Taila Matra Basti (60 ml per rectal route for 7 days after menstruation) for 3 months, while Group B (103 patients) received Mefenamic acid (500 mg) and Dicyclomine hydrochloride (20 mg) as needed. Primary outcome measures were pain intensity (Visual Analog Scale, VAS) and pain duration. Secondary outcome measures focused on associated symptoms (MDQ, VMS), quality of life (SF-36), and consumption of analgesic. Safety was assessed via laboratory investigations.

Results: Significant improvements were observed in pain intensity (VAS: 2.98 to 0.83) and pain duration (2.20 to 0.15) in Group A compared to Group B (VAS: 2.84 to 2.42, pain duration: 2.53 to 2.32). Group A showed better improvements in associated symptoms, quality of life (SF-36 scores), and analgesic consumption. Both treatments were well-tolerated, with no severe adverse effects reported.

Conclusion: Ayurvedic treatment regimen of Kuberakshadi Vati and Dashmoola Taila Matra Basti proved more effective than conventional pharmacological treatments in managing primary dysmenorrhea.

Clinical Trial Registry of India (CTRI/2020/07/026892)

Keywords: Dashmoola Taila, Dysmenorrhea, Kashtartava (primary dysmenorrhea), Kuberaksha Vati

How to cite this article: Dhiman K., Clinical Efficacy of Ayurvedic Treatment Regimen in the Management of Kashtartava (Primary Dysmenorrhea) – A Randomized Controlled Clinical Trial. Int J Drug Deliv Technol. 2026;16(77s): 852; DOI: 10.25258/ijddt.16.77s.101

Introduction

Dysmenorrhea is the most common gynecological problem faced by females, causing significant discomfort and anxiety for her as well as her family [1]. It is characterized by severe abdominal pain during menstruation manifesting as cyclical pattern. It is commonly classified as primary in the absence of co-existent pathology and secondary if there is an identifiable pathological condition [2]. A systematic review revealed that about 25%–50% of adult women and about 75% of adolescents experience pain during menstruation, with 5%–20% reporting severe dysmenorrhea or pain severe enough to prevent them from carrying out day-to-day activities, associated with psychological, physical, behavioral, and social distress [3],[4].

The incidences of dysmenorrhea are greater than any other gynecological illness. Thirty-eight percent of women frequently consume medical treatment to treat their symptoms. Dysmenorrhea accounted for 600 million lost work hours and $2 billion in lost productivity per annum [5],[6]. Analgesics, antispasmodics, and/or oral contraceptive pills may not provide a long-lasting solution and may lead to serious adverse effects. Hence, there is a need for a safe and long-lasting treatment regimen that can relieve the entire symptom complex of primary dysmenorrhea.

In Ayurvedic classics, it is stated that pain cannot happen without Vata dosha (bio-energetic force responsible for movement) [8],[9],[10]. For the pathogenesis of gynecological problems, Vata dosha, particularly Apana Vata (subtype of Vata controlling downward movements), is responsible. Improper diet and lifestyle aggravates all types of Vata dosha and the digestive fire (Agni) as well. Hence, to combat the problem, Vata dosha should function normally. Classical Ayurvedic literature highlights management measures such as Vatanulomaka (Vata pacifying), Shoolaprashmanan (anodyne/pain-relieving) drugs, as well as the role of Basti chikitsa (therapeutic enema) [10].

Keeping this in view, two well-known Ayurvedic preparations were selected for this study: Kuberaksha Vati [AFI, Part-3] (Vata pacifying herbal tablet) and

Matra Basti of Dashmoola Taila (medicated oil enema), which has been advocated for management of conditions included under Kashtartava (primary dysmenorrhea). The efficacy of Kuberaksha Vati was verified and compared with Dashmoola Taila Matra Basti.

Materials and Methods:
The study was a randomized open-label interventional clinical trial of 205 patients with dysmenorrhea. Ethical clearance was obtained from the Institutional Ethics Committee, and the study was registered under the Clinical Trial Registry of India (CTRI/2020/07/026892). Written consent of patients was obtained before initiation.

Primary and Secondary Outcome Measures:
Primary outcome measures: Changes in intensity of menstrual pain using VAS scale (Visual Analog Scale) at baseline, and at the end of 1st, 2nd, 3rd, 4th, 5th, and 6th menstrual cycles.
Secondary outcome measures: Changes in other signs and symptoms using Verbal Multi-dimensional Scoring System (VMS) and Menstrual Distress Questionnaire (MDQ), changes in quality of life using Health Survey – SF – 36 Questionnaire (RAND), and frequency of analgesic intake, assessed at baseline and after each menstrual cycle up to six cycles.

Eligibility Criteria:
- **Inclusion:** Females aged 15–24 years, at least 3 painful cycles in the last 6 cycles (21–35 days), intensity of pain ≥40 mm on VAS, menstrual pain duration ≥1 day, willing to participate and provide informed consent.
- **Exclusion:** Secondary dysmenorrhea, prolonged medication (>2 weeks) with corticosteroids, antidepressants, anticholinergics, systemic/chronic illness affecting menstrual cycle, planning pregnancy during study, lactation, mental/psychiatric illness.

Randomization: Patients were randomly assigned into two groups using a random number generator. Of 205 patients enrolled from XXXXXXXXXXXXX, 86/102 completed in Group A and 85/103 in Group B.

Investigations: Baseline hemogram (hemoglobin, total leukocyte count, platelet count), liver function test, kidney function test, and thyroid function test were performed. Urine routine microscopy, stool routine microscopy, and ultrasonography of the lower abdomen were done before and after treatment. Investigations were repeated at the end of 90th day (end of intervention).

Sample Size: Calculated based on expected improvement in 95% of patients in allopathic group and 80% in Ayurvedic intervention group, with 95% confidence level ($\alpha = 0.05$) and 80% power. Considering 20% dropout, 90 patients per group were enrolled.

Interventions:
- **Group A (Ayurvedic):**

1.Kuberaksha Vati – 1 g (500 mg × 2 vati) three times a day orally with lukewarm water after food.
2.Dashmoola Taila Matra Basti (medicated oil enema) – 60 ml/day, per rectal route for 7 days after cessation of bleeding.
- Group B (Control):

Mefenamic acid 500 mg + Dicyclomine hydrochloride 20 mg tablet, one tablet as needed per pain episodes.

Drug Procurement and Preparation: The trial drugs (Kuberaksha Vati & Dashmoola Taila) were procured from IMPCL, Ministry of AYUSH, a GMP-certified Ayurveda Pharmaceutical Company. Control drug was procured from the market through the Institutional Purchase Withdrawal criteria: Withdrawal criteria was development of any adverse drug effect (ADE) or adverse drug reaction (ADR), non-compliance of the treatment regimen (minimum 80% compliance is essential to continue in the study.), the patient herself wants to withdraw from study or the condition worsens, if the patient develops any other health ailments mentioned in exclusion criteria during the trial. Every subject was free to withdraw from the trial at any point of time for any reason. The reason for withdrawal was recorded in CRF, dated and signed.
Follow up assessment: Patients visited for follow-up on day 1 base line, at the end of 1st, 2nd, 3rd, 4th, 5th, and 6th menstrual cycle. Changes in signs and symptoms were noted by using Verbal Multi-dimensional scoring system and Menstrual Distress questionnaire (Time frame: At base line, at the end of 1st, 2nd , 3rd , 4th, 5th, and 6th menstrual cycle), changes in the quality of life of the study participants by using Health Survey – SF – 36 Questionnaire (RAND) (Time frame: At baseline, 90th and 180th day), to check decreased frequency of analgesic intake (Time frame: At base line, At base line, at the end of 1st, 2nd, 3rd, 4th, 5th, and 6th menstrual cycle).

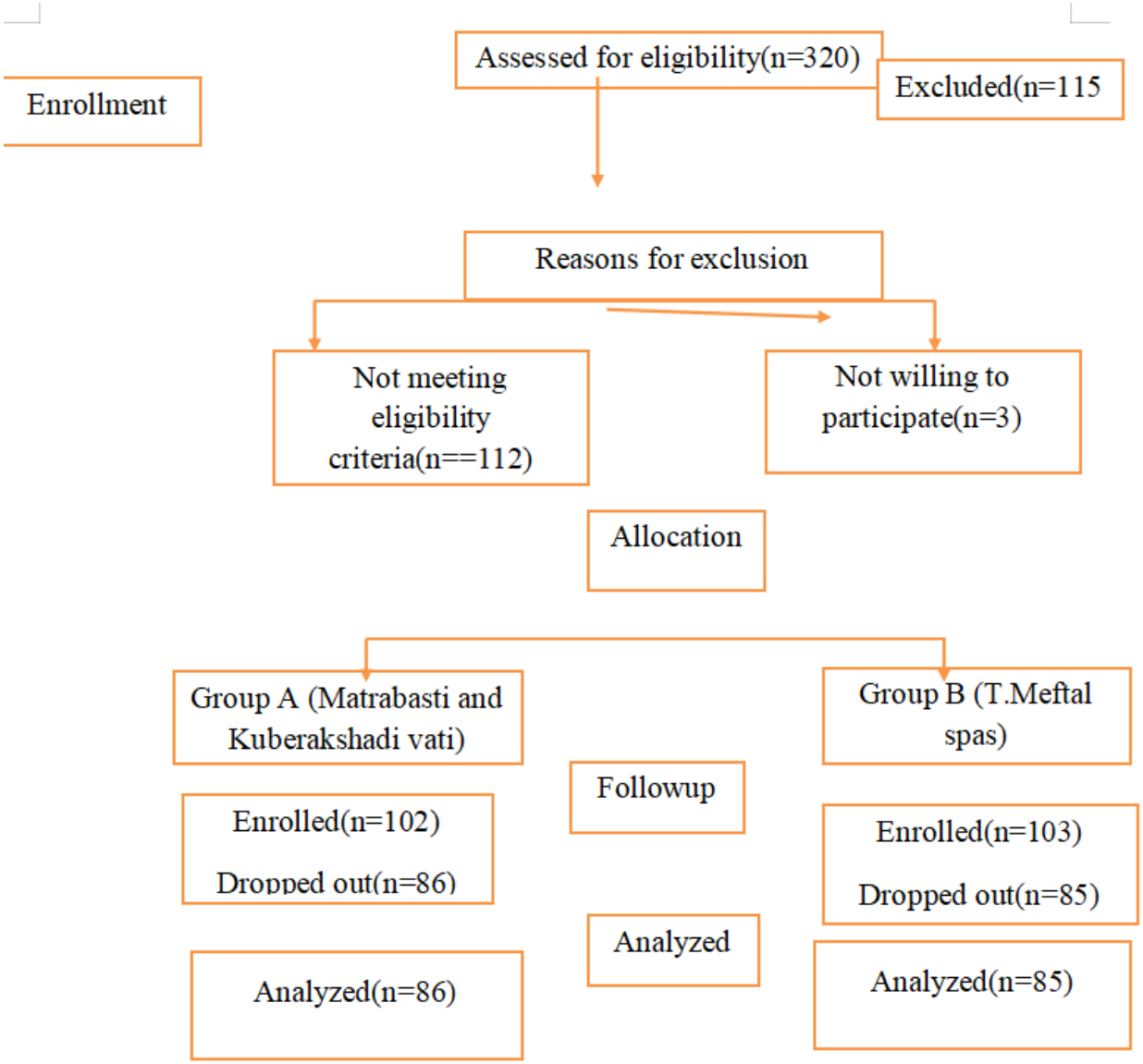
Statistical test used
For descriptive statistics and nonparametric data, the Chi-square test, Mann–Whitney test, and Wilcoxon match pairs test were used, and for parametric data, independent t-tests and dependent t tests were used.

Results:
- Both the groups showed improvement in menstrual pain assessed through VAS scale. Improvement is significantly more in Group A (2.98 to 0.83) than in Group B (2.84 to 2.42), comparison between Group A Vs Group B ($F=132.8$, $P = 0.000$)
- Duration of pain: Improvement is significantly more in Group A (2.20 to 0.15) than in Group B (2.53 to 2.32), comparison between Group A Vs Group B ($F=167.4$, $P = 0.000$)
- Significant improvement seen in clinical features associated with dysmenorrhea in group A when compared to group B.
- All the lab parameters were in normal range in both groups after the end of treatment, so it can be

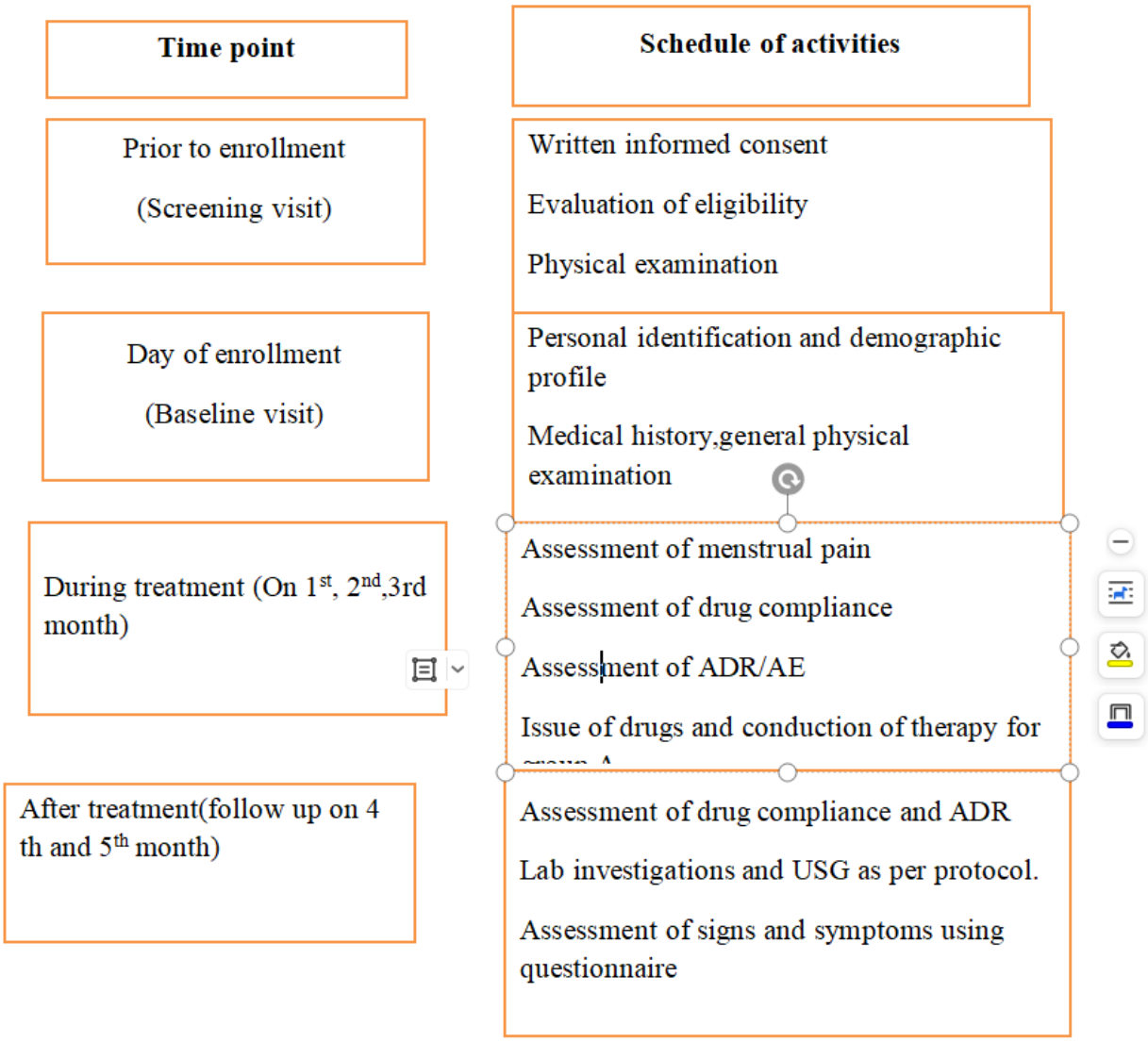
concluded that medicines from both groups are safer to administer.

- Group A demonstrates a better response across all examined measures:
  - MDQ and VMS scores: Significant decreases indicating reductions in associated complaints during menstruation, systemic symptoms, use of analgesics.
  - SF36 scores: A significant increase, indicating an improvement in quality of health.
- Group B also shows improvements but to a lesser extent in comparison to Group A, especially in terms of quality of health as reflected by SF36 scores.

Considering the comprehensive analysis of MDQ, VMS, and SF36 scores, Group A is observed to have a more favorable overall response to treatment, balancing symptom relief with an enhancement in quality of life.



Outflow of participants in the study



Demographic data: In the present study, 34.63% belonged to age group 16–20 years; 24.88%, 21.95%, and 18.54% belonged to age groups 21–25, 26–30, and 31–35 years respectively. 91.22% patients were Hindu, 8.29% Muslim, and 0.49% Christian. 84.39% were from urban areas, 15.12% from rural areas, and 0.49% from slum areas. 37.56% were in higher secondary schools, 31.22% pursuing graduation, 9.76% in post-graduation, 7.80% were studying in primary schools, 7.80% studying secondary schools, and 5.85% uneducated. 80.98% were middle class, 16.10% lower middle class, and 2.92% upper middle class. 29.27% had undergone allopathic treatment, 5.85% consulted for Ayurvedic treatment, 2.44% had taken both Ayurvedic and allopathic treatment, and 1.46% other medicines.

Clinical profile: All patients had painful menstruation. 84.88% reported hypogastric pain, 63.90% pain in front of thigh, and 44.39% pain on the inner thigh. 91.71% had cramping pain, 10.73% diffuse dull ache. 75.12% experienced pain with menstruation onset, 46.34% a few hours before menstruation, and 41.46% had pain for only one day. Before treatment, 11.22% reported 10/10 pain on VAS, 30.73% 9/10, 31.22% 8/10, 15.61% 7/10, 6.83% 6/10, and 3.41% 5/10.

Discussion:

Primary dysmenorrhea is a common gynecological problem which considerably impacts the quality of life of an individual. Management gives emphasis upon pain relief, to reduce inflammation if any, and to improve overall health. The successful management of primary dysmenorrhea requires a personalized treatment plan tailored to the individual needs and preferences of the patient.

In Ayurveda it is mentioned that release of Artava (menstrual blood) should be without pain. When pain is

associated with Artava (menstrual blood), it is named Kashtartava (painful menstruation/primary dysmenorrhea). In Several disease conditions, Kashtartava is mentioned as a symptom. Among them, Vataja Yonivyapada (Vata-induced gynecological disorders), Vataja Artavadushti (Vata-induced menstrual dysfunction), Udavarta (upward movement of Vata causing abdominal pain), Suchimukhi (uterine channel disorders), and Artava Kshaya (deficiency of menstrual blood) can be correlated with primary dysmenorrhea based on their symptoms. Apart from that, the Nidanas (causative factors) given for these conditions, which reflect the clinical picture of Kashtartava, are also incorporated.

Samprapti (pathogenesis) of Kashtartava can be explained with causes of Vata Prakopa (Vata aggravation) such as Dathu kshaya (tissue depletion), Kopa (exacerbation), and Margavarodha (obstruction in channels). All disease conditions that come under primary dysmenorrhea can be explained well with these Samprapti (pathogenesis). Additionally, it correlates with dysmenorrhea and covers most theories postulated as etiopathogenesis of primary dysmenorrhea.

There are several important aspects to consider regarding the efficacy of Basti (therapeutic enema) for Kashtartava. According to Acharya Charaka, Vata (bio-energetic force responsible for movement) plays a crucial role in all forms of Yoni roga (gynecological disorders) [11],[12],[13]. He states that women typically do not experience gynecological issues unless influenced by aggravated Vata. Therefore, the primary focus should be on alleviating Prakupita Vata (aggravated Vata). Kashtartava is a Pakvashayagatavyadhi (disease located in the large intestine), as Pakvashaya (large intestine/colon) being the primary seat of Vata. Pain is a defining characteristic of Kashtartava, it is mentioned in the Susruta Samhita that pain cannot happen without the involvement of Vata. These referenced indicates significant connection between Vata dosha and Kashtartava.

Basti (therapeutic enema) is one of the most effective treatment modality to reduce Vata dosha having direct approach to the Pakvashaya (large intestine/colon) in comparision to other treatment modalities. Mucosal surface area of the human colon is around 2000 cm^2, but the overall absorptive area is larger as colonic crypt cells can absorb as well as secrete [14],[15],[16]. Rectum has a rich blood and lymph supply, and drugs can cross the rectal mucosa like any other lipid membrane in the transrectal route. Consequently, entering general circulation, medicines of basti may have an effect on the entire body, including neurological or gastrointestinal receptors. They may increase local enzyme or neurotransmitter secretion, affect bacterial flora, and increase endogenous vitamins such as B12 and K. Drug absorption is determined by physicochemical properties, formulation, and route of administration. Rectal administration offers faster absorption and higher bioavailability.

Consumption of Vata Prakopaka Aahara and Vihara (Vata aggravating diet and lifestyle) aggravate Vata dosha. This unbalanced Vata, characterized by Ruksha (dry), Sheeta (cold), and Sukshma (subtle) properties, spreads through Rasavaha Srotasa (plasma channels), resulting into dysfunction of Rasavaha, Raktavaha, and Artavavaha srotas(channels). Dosha-Dushya interaction in Garbhashaya (uterus) affects on contraction and expansion movements of uterine muscles, mimicking dysrhythmia that may impair menstrual blood flow, and contribute to Kashtartava.

Kuberaksha Vati is indicated in Shotha (inflammation), Krimi (worms), Udarashoola (abdominal colic), and Agnimandya (digestive weakness). Harita Samhita has mentioned in Udarashoola. Dashmoola Taila is helpful for Kashtartava, being Tridoshanashaka (pacifying all three doshas), particularly effective against Vata imbalances. It helps to eliminate Avarana (obstruction) of Kapha and Pitta in the Artavavaha Srotasa (menstrual channels) and nourishes the genitourinary system by supporting the hypothalamo-pituitary-ovarian axis.

Ingredients of Kuberaksha Vati include Latakaranja (Caesalpinia crista), Shunti (dry ginger), Hingu (asafoetida), Rason (garlic), and Sauvarchala (alkaline salt), which are Kapha-Vata shamaka (pacifying Kapha and Vata), with Rochan, Deepan, Pachan, Anulomak properties (digestive, carminative, laxative, Vata normalizing). Some are Ushna, Tikshna, Sara (hot, sharp, light). Together, they normalize Apana Vayu, restoring functions in the Apana Kshetra (pelvic organs). Latakaranja alleviates colic, acts Tridosha shamaka (pacifying all three doshas), Vedanasthapak (analgesic), Raktashodhak (blood purifier), and Pramehaghna (antidiabetic). It also contains Bonducin – glycoside with antitumor, analgesic, and anti-inflammatory action [25],[26],[27],[28].

Kuberaksha Vati (Table 1 & Table 2) contains Latakaranja, Shunthi, Hingu, Sauvarchala, with Rasona swarasa as Bhavana dravya (levigating medium). Quantities per classical texts: Latakaranja 1 karsha (12 g), Shunthi 1 karsha (12 g), Hingu ½ karsha (6 g), Sauvarchala ½ karsha (6 g).

Meftal Spas tablets relieve uterine contractions by inhibiting cyclo-oxygenase enzymes. Long-term use may cause stomach ulcers, black or sticky stools, stomach pain, vomiting blood, angina, shortness of breath, and slurred speech.

Conclusion:

Analysis of results shows that statistically and clinically, Group A (Matra Basti with Dashmoola Taila and Kuberaksha Vati) achieved better outcomes compared to Group B (Meftal Spas tablets).

Author's contribution

Authour1 - Conceptualization, Methodology/ Study design, Validation, Form analysis, Investigation, Resources, Data curation, Writing - original draft, Writing - review and editing,

Authour 2- Formal analysis, writing review and editing.

Supervision – Authour 3, Authour 4

Data availability statements: All gathered data is appropriately preserved electronically or physically as

needed. They are kept private and accessible only to the relevant author, who may make them available in the right situations.

Financial support and sponsorship – ICMR and CCRAS

Acknowledgement

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Conflicts Of Interest -The authors have no conflict of interest.

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Table – 1 CONTENTS OF KUBERAKSHA VATI -

Content	Latin Name	Family	Part used	Ratio	Form
Lata Karanja	Caesalpinia crista Linn	Leguminosae		4 parts	Churna
Shunthi	Zingiber officinal	Zingiberaceae	Rhizome	4 parts	Churna
SauvarchalaLavana	Unaqua sodium chloride			2 parts	Churna
Hingu	Ferulafoetida	Umbellifereae	Resin	2 parts	Churna
Lashuna	Allium sativum	Lileaceae	Bulb	2 parts	Swarasa

Table – 2 Rasa Panchak of individual drugs of KuberakshaVati

Drug	Rasa	Guna	Virya	Vipaka	Doshaghnata
Lata Karanja	Katu, Tikta, Kashaya	Laghu, Tikshna	Ushna	Katu	TridoshaShamak
Shunthi	Katu	Laghu, Snigdha, Tikshna	Ushna	Madhur	KaphavataShamak
Sauvarchala Lavana	Lavana	Vishad, Laghu, Sukshma, Snigdha	Ushna	Madhur	Vatahara
Hingu	Katu, Tikta	Tikshna, Laghu, Snigdha	Ushna	Katu	VatakaphaharaPittavardhak
Lashuna	AmlavarjitPancharasa	Snigdha, Guru, Picchila, Tikshna, Sara	Ushna	Katu	VatakaphaharaPittavardhak