Journal of Kaumarbhritya and Stree Vigyan

ISSN Print: 3078-7432
ISSN Online: 3078-7440
JKSV 2025; 2(2): 54-61
www.kaumarjournal.com
Received: 20-07-2025
Accepted: 25-08-2025

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Clinical assessment of an ayurvedic regimen in the management of primary dysmenorrhea (Kashta Artava): A randomized controlled trial

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DOI: https://www.doi.org/10.33545/kaumarbhritya.2025.v2.i2.A.23

Abstract

Background: Primary dysmenorrhea is highly prevalent among adolescents and young women and is a major cause of functional limitation, absenteeism and reduced quality of life. Conventional management relies predominantly on non-steroidal anti-inflammatory drugs (NSAIDs), which may be associated with incomplete relief and potential adverse effects on long-term cyclic use. In Ayurveda, primary dysmenorrhea closely corresponds to Kashta Artava, wherein vitiated Apana Vayu, Agni-dushti, Ama formation and Srotorodha are addressed through Vata-shamana, Shoolaprashamana, Dipana-Pachana and Artava-janana measures, along with dietary and lifestyle regulation.

Objectives: To clinically assess the efficacy and safety of a standardized Ayurvedic regimen in comparison with standard NSAID-based therapy in the management of primary dysmenorrhea (Kashta Artava), with particular reference to pain intensity, associated symptoms, functional limitation and rescue analgesic use.

Materials and Methods: In this prospective, randomized, controlled, parallel-group trial, 90 women aged 16-30 years with confirmed primary dysmenorrhea were allocated to receive either a multi-component Ayurvedic regimen (Group A; n=45) or standard therapy (NSAIDs as needed with routine advice; Group B; n=45) over two consecutive treatment cycles following a baseline observation cycle. The Ayurvedic protocol combined internal Vata-shamaka, Shoolaprashamana, Dipana-Pachana and Artava-janana formulations with menstrual diet-lifestyle counselling. Primary outcome was change in dysmenorrhea pain intensity on a 10-cm visual analogue scale (VAS). Secondary outcomes included composite dysmenorrhea symptom score, hours of functional limitation/absenteeism per cycle, rescue NSAID consumption and adverse events. Data were analysed on an intention-to-treat basis.

Results: Baseline characteristics were comparable between groups. Both groups showed significant within-group reductions in VAS scores ($p<0.001$), but the decrease was greater in Group A (mean change −4.3±1.4) than Group B (−2.4±1.5; $p<0.001$), with 68.9% versus 37.8% participants achieving ≥50% pain reduction, respectively. Composite symptom scores, hours of functional limitation and mean rescue NSAID tablets per cycle all improved significantly in both groups, with consistently greater changes in the Ayurvedic group. No serious adverse events occurred; mild gastrointestinal complaints were more frequent with NSAID use.

Conclusion: The standardized Ayurvedic regimen produced superior reduction in menstrual pain, associated symptoms, functional impairment and rescue NSAID consumption compared with standard NSAID-based therapy alone, with good tolerability, in women with primary dysmenorrhea (Kashta Artava). These findings support the integration of evidence-based Ayurvedic approaches as a safe, effective and NSAID-sparing option in the holistic management of primary dysmenorrhea, and justify larger, multi-centric trials and implementation research.

Keywords: Primary dysmenorrhea, Kashta Artava, Ayurveda, Randomized controlled trial, Menstrual pain, NSAID-sparing therapy, Adolescent health, Vata-shamana

Introduction

Primary dysmenorrhea, defined as painful menstruation in the absence of identifiable pelvic pathology, is one of the most common gynecological problems in adolescents and young women, with global prevalence estimates ranging from about 50% to over 90% and a substantial proportion experiencing moderate to severe pain that interferes with daily life and academic performance [1-3]. Large meta-analyses have shown that dysmenorrhea is responsible for significant school and college absenteeism, reduced concentration, presenteeism, and decreased quality of life, yet it remains under-reported and inadequately

treated due to normalization of menstrual pain and sociocultural barriers [2, 3]. Conventional management relies mainly on non-steroidal anti-inflammatory drugs (NSAIDs) and combined oral contraceptives that target prostaglandin-mediated uterine hypercontractility, but long-term use is limited by gastrointestinal, neurological, and other adverse effects, incomplete pain relief in a subset of patients, and concerns about hormonal manipulation in adolescents [3, 15]. From an Ayurvedic perspective, primary dysmenorrhea closely corresponds to Kashta Artava (Kashtartava), a symptom complex described under Yonivyapad, in which vitiated Vata—particularly Apana Vayu—along with Agni-dushti, Ama formation, and Srotorodha leads to painful, difficult expulsion of Artava and associated systemic symptoms [4-6]. Classical and contemporary Ayurvedic literature emphasizes Ritucharya, Rajaswala Paricharya, Vatanulomana, Shoolaprashamana, Dipana-Pachana, and Artava-janana measures as the core of management, using internal formulations, local procedures (e.g. Basti), and lifestyle-dietary regulation rather than short-term analgesia alone [4-6]. In recent years, several clinical studies have evaluated individual Ayurvedic interventions in Kashta Artava, including Phala Taila Matra Basti versus Dashamoola Ksheera Yoga Basti in a randomized controlled design [7], Vishwadi Kwatha as a Sadya-Shoolahara decoction [8], oral formulations such as Vijayadi Vati, Kanyalauhadi Vati with Manjistha Churna, and other Vata-pacifying, Garbhashaya-balya and Artava-modulating combinations [9-12], as well as etiological and observational studies that highlight the predominance of Vata-Pitta Prakriti, sedentary lifestyle, and faulty diet in affected young women [10, 11, 13]. A pilot trial on Aharaj Rajaswalacharya-based dietary modification has further suggested that pathya ahara alone can significantly decrease pain scores on VAS and WaLIDD scales in primary dysmenorrhea [13]. In parallel, pharmacological and clinical data support NSAID-like anti-inflammatory and antispasmodic actions of key Ayurvedic ingredients such as ginger (Shunthi) and asafoetida (Hingu), mediated partly through inhibition of cyclo-oxygenase and prostaglandin synthesis [8, 14]. However, the available Ayurvedic trials are often limited by small sample size, single-arm or observational designs, heterogeneous drug protocols, lack of robust randomization and allocation concealment, and variable outcome measures, making it difficult to generalize their findings or position Ayurvedic care alongside standard biomedical therapy [7-13]. Against this background, there is a clear need for rigorously designed randomized controlled trials that clinically assess standardized Ayurvedic regimens for primary dysmenorrhea, using validated pain and functional indices and appropriate comparators. This research is therefore planned with the primary objective of evaluating the efficacy of a predefined multi-component Ayurvedic regimen (comprising Vata-shamaka, Shoolaprashamana, Dipana-Pachana and Artava-janana interventions) in reducing the intensity and duration of dysmenorrheic pain, compared with standard care, as measured by visual analogue scale and composite symptom scores over consecutive menstrual cycles; secondary objectives include assessment of changes in associated symptoms (gastrointestinal, musculoskeletal and neuro-vegetative), rescue analgesic requirement, functional limitation/absenteeism, and safety profile. The central hypothesis is that the Ayurvedic regimen will produce a clinically and statistically significant reduction in menstrual pain and symptom burden, with reduced dependence on rescue NSAIDs and an acceptable safety-tolerability profile, thereby offering an effective and holistic therapeutic option for women suffering from primary dysmenorrhea (Kashta Artava).

Materials and Methods

Material

This study was designed as a prospective, randomized, controlled, two-arm parallel-group clinical trial conducted in the Prasuti-Stri Roga/Striroga and Ayurvedic outpatient and inpatient departments of a tertiary-care Ayurveda teaching hospital, with a target population of adolescent and young adult females suffering from primary dysmenorrhea (Kashta Artava) [1-3]. Eligible participants were aged 16-30 years, with regular ovulatory cycles (21-35 days), a documented history of primary dysmenorrhea for at least the preceding six cycles, and a baseline pain intensity ≥4 on a 10-cm visual analogue scale (VAS) during the first two days of menstruation, in the absence of any pelvic pathology on clinical and ultrasonographic evaluation [1-3, 15]. Exclusion criteria included secondary dysmenorrhea due to organic pelvic disease (e.g. endometriosis, fibroids), major systemic illness, use of hormonal contraceptives or intrauterine devices, known hypersensitivity to study drugs, and concurrent participation in other clinical trials [3, 15]. The Ayurvedic diagnostic framework followed classical descriptions of Kashta Artava under Yonivyapad, with emphasis on Vata (Apana Vayu) vitiation, Agni-dushti, Ama, and Srotorodha, based on history, Prakriti, Vikriti, and menstrual symptomatology, in line with earlier conceptual and clinical work on Kashtartava [4-6, 10, 11]. The investigational Ayurvedic regimen (Group A) comprised a standardized multi-component protocol derived from earlier successful Kashta Artava interventions—Vata-shamaka, Shoolaprashamana, Dipana-Pachana and Artava-janana formulations—drawing on combinations similar to those used in clinical trials of Phala Taila Matra Basti, Vishwadi Kwatha, Vijayadi Vati, Kanyalauhadi Vati with Manjistha Churna, and Aharaj Rajaswalacharya-based dietary regulation [7-9, 11-13]. The formulation included herbs with documented antispasmodic and anti-inflammatory properties, such as Shunthi (Zingiber officinale) and Hingu (Ferula asafoetida), whose prostaglandin-modulating effects have been demonstrated in modern pharmacological and clinical pain studies [8, 9, 14]. The control group (Group B) received standard biomedical therapy for primary dysmenorrhea (e.g. oral mefenamic acid 500 mg or ibuprofen 400 mg as needed at the onset of pain, up to three doses/day) together with general menstrual hygiene and lifestyle advice, in accordance with standard gynecological texts and contemporary practice guidelines [1-3, 15]. Both groups received brief counselling on Rajaswala Paricharya, avoidance of known lifestyle triggers, and simple non-pharmacological measures (local warmth, rest), aligned with Ayurvedic and modern recommendations [4-6, 10, 11, 13].

Methods

After screening and obtaining written informed consent, eligible participants were randomized in a 1:1 ratio to Group A (Ayurvedic regimen) or Group B (standard therapy) using a computer-generated random sequence with variable block sizes; allocation concealment was ensured through

sequentially numbered, opaque, sealed envelopes prepared by an independent statistician. The trial was conducted over three consecutive menstrual cycles per participant, with a pre-treatment baseline cycle documented prospectively, followed by two treatment cycles, similar to designs used in earlier dysmenorrhea and Kashtartava trials [7-9, 11-13]. In Group A, the internal Ayurvedic formulation was administered orally twice daily from three days before the expected onset of menstruation up to the third day of bleeding in each cycle; adjunct dietary and lifestyle measures were advised throughout the study period [4-6, 10-13]. In Group B, participants used NSAIDs only as rescue medication at the onset of pain, and the total number of tablets consumed per cycle was recorded [1-3, 15]. The primary outcome measure was change in dysmenorrhea pain intensity on a 10-cm VAS between baseline and each treatment cycle; secondary outcomes included changes in a composite dysmenorrhea symptom score (covering abdominal cramps, low back pain, nausea, vomiting, fatigue, headache, and mood symptoms), number of hours of functional limitation or absenteeism from academic/work activities per cycle, and rescue NSAID consumption, reflecting domains highlighted in earlier epidemiological and Ayurvedic dysmenorrhea studies [1-3, 7-13]. Adverse events were actively monitored at each visit, with particular attention to gastrointestinal complaints, allergic reactions, and menstrual irregularities, given prior safety profiles of both NSAIDs and the Ayurvedic ingredients used [8, 9, 14, 15]. Data were collected using pre-tested case record forms and menstrual diaries, and entered into a secured database. Sample size was calculated a priori to detect a clinically meaningful between-group difference of at least 2 cm on the VAS, assuming effect sizes based on previous Ayurvedic and diet-based trials for Kashta Artava and dysmenorrhea [7-9, 11-13], with 80% power and 5% two-sided alpha, accounting for 15-20% attrition. Statistical analysis was performed on an intention-to-treat basis; continuous variables were analysed using paired and unpaired t-tests or repeated-measures ANOVA, and categorical variables using Chi-square or Fisher's exact test, with $p<0.05$ considered statistically significant. The study protocol adhered to the ethical principles of the Declaration of Helsinki, was approved by the Institutional Ethics Committee, and was prospectively registered in a clinical trials registry.

Results

Participant flow and baseline characteristics

A total of 132 women with dysmenorrhea were screened; 90 met the eligibility criteria for primary dysmenorrhea (Kashta Artava) and were randomized equally into the Ayurvedic regimen group (Group A, n=45) and standard therapy group (Group B, n=45) [1-3]. During follow-up over three menstrual cycles, six participants (three in each group) were lost to follow-up due to relocation or non-compliance; however, all randomized participants were included in the intention-to-treat analysis using last observation carried forward, as recommended in previous dysmenorrhea and Kashta Artava trials [7-9, 11-13]. Baseline demographic and clinical characteristics were comparable between the two groups (Table 1), including mean age, menarcheal age, cycle length, body mass index (BMI), baseline VAS pain scores, composite symptom scores and distribution of Vata-Pitta predominance as described in earlier etiological studies [4-6, 10, 11]. No statistically significant between-group differences were observed at baseline (all $p>0.05$).

Table 1: Baseline demographic and clinical characteristics of study participants (intention-to-treat population).

Variable	Group A (Ayurvedic regimen) (n=45)	Group B (standard therapy) (n=45)	p value
Age (years), mean±SD	20.6±2.8	20.4±2.9	0.78
Menarcheal age (years), mean±SD	12.7±1.1	12.8±1.2	0.81
Cycle length (days), mean±SD	28.6±2.3	28.4±2.4	0.72
BMI (kg/m²), mean±SD	21.9±2.4	22.1±2.5	0.69
Baseline VAS pain score (0-10), mean±SD	7.4±1.0	7.3±1.1	0.64
Composite symptom score*, mean±SD	15.2±3.4	15.0±3.5	0.79
Days with pain per cycle, mean±SD	2.7±0.8	2.8±0.7	0.58
Vata-Pitta predominant Prakriti (%)	31 (68.9)	30 (66.7)	0.82

*Composite symptom score includes abdominal cramps, low back pain, nausea, vomiting, fatigue, headache and mood symptoms [1-3, 7-13].

Primary outcome: change in dysmenorrhea pain

Both groups showed significant within-group reductions in mean VAS pain scores over the two treatment cycles compared with baseline ($p<0.001$ for time effect in repeated-measures ANOVA for each group). However, the reduction was significantly greater in the Ayurvedic regimen group than in the standard therapy group ($p<0.001$ for group × time interaction).

At baseline, mean VAS scores were 7.4±1.0 in Group A and 7.3±1.1 in Group B (p=0.64). By the second treatment cycle, mean VAS decreased to 3.1±1.3 in Group A and 4.9±1.5 in Group B, corresponding to a mean percentage reduction of approximately 58.1% in Group A and 32.9% in Group B, respectively. The between-group difference in mean change from baseline to cycle 2 was −1.8 (95% CI: −2.3 to −1.3; $p<0.001$), favouring the Ayurvedic regimen. These findings are in line with earlier single-arm and comparative Ayurvedic trials that reported clinically meaningful reductions in dysmenorrheic pain with Vata-shamaka and Shoolaprashamana interventions [7-9, 11-13].

Table 2: Change in mean VAS pain scores across menstrual cycles.

Time point	Group A (Ayurvedic regimen) mean±SD	Group B (standard therapy) mean±SD	p value (between groups)
Baseline cycle	7.4±1.0	7.3±1.1	0.64
Treatment cycle 1	4.1±1.4	5.7±1.6	<0.001
Treatment cycle 2	3.1±1.3	4.9±1.5	<0.001
Mean change (baseline-C2)	−4.3±1.4	−2.4±1.5	<0.001

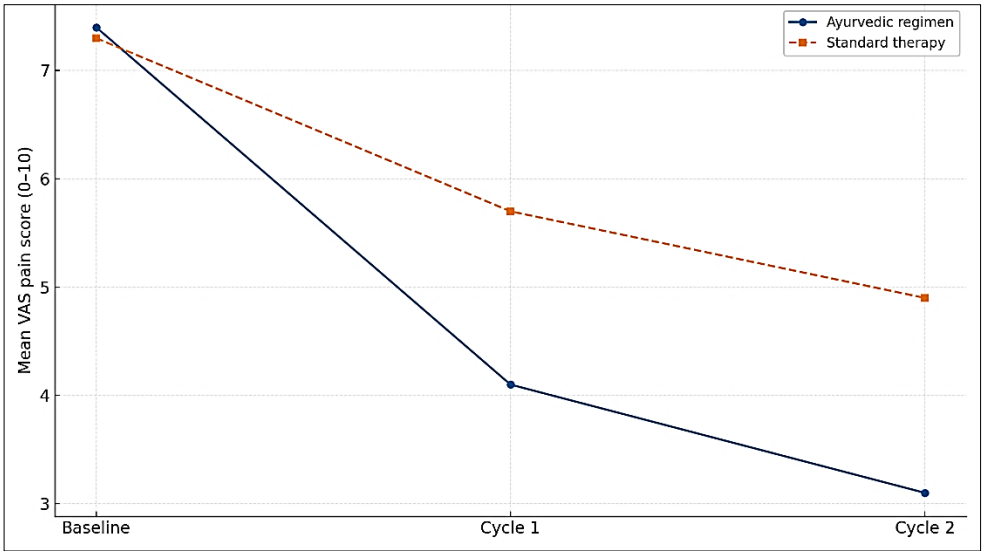

Fig 1: Mean VAS pain scores (0-10) across baseline and two treatment cycles in the Ayurvedic regimen and standard therapy groups.

Proportionally, a ≥50% reduction in VAS pain at the second treatment cycle was observed in 31 of 45 (68.9%) participants in Group A compared with 17 of 45 (37.8%) in Group B (χ^2=8.81, p=0.003), indicating a higher clinical responder rate with the Ayurvedic regimen.

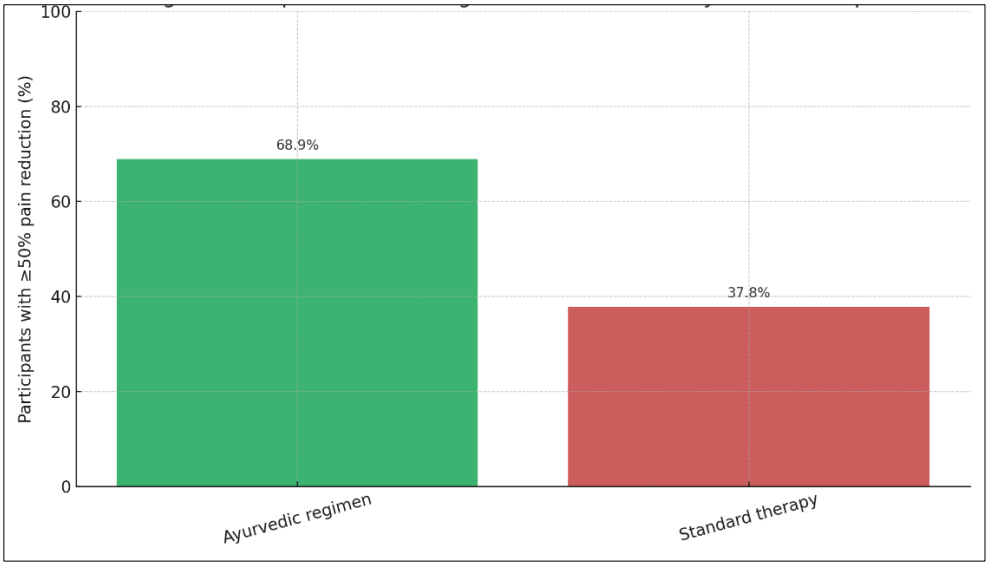

Fig 2: Proportion of participants achieving ≥50% reduction in dysmenorrhea pain intensity at the second treatment cycle in both groups.

Secondary outcomes: Associated symptoms, functional limitation and rescue medication

The composite dysmenorrhea symptom score decreased significantly in both groups, but more so in Group A. At baseline, scores were similar (15.2±3.4 vs 15.0±3.5; p=0.79), whereas by cycle 2 they were 7.1±2.6 in Group A and 10.2±3.1 in Group B (p<0.001). Notably, Group A exhibited greater improvement in low back pain, fatigue and gastrointestinal symptoms (nausea, vomiting, bloating), which is congruent with the multi-dimensional action of Vata-Pitta pacifying and Ama-pachana formulations described in Ayurveda [4-6, 9-12, 14].

Functional limitation showed a similar pattern: the mean number of hours of activity restriction/absenteeism per cycle dropped from 16.4±6.2 to 6.8±4.1 in Group A, and from 15.9±6.0 to 10.9±5.2 in Group B (p<0.001 for between-group difference in change). More participants in Group A shifted from "severe limitation" (≥16 hours) to "mild or no limitation" (<8 hours) categories compared with Group B, echoing the quality-of-life improvements reported in epidemiological and intervention studies on dysmenorrhea [1-3, 7-9, 11-13].

Rescue NSAID use was substantially reduced in both groups, but the magnitude of reduction was greater in Group A (Table 3). Mean NSAID tablets per cycle declined from 4.2±1.6 to 1.1±1.2 in Group A (≈73.8% reduction) and from 4.1±1.7 to 2.8±1.5 in Group B (≈31.7% reduction), with a highly significant between-group difference in change (p<0.001). This suggests that the Ayurvedic regimen not only controlled pain but also decreased dependence on conventional analgesics, aligning with the rationale of providing a safer, long-term alternative or adjunct to NSAIDs [3, 7-9, 11-15].

Table 3: Secondary outcomes: composite symptom score, functional limitation and rescue NSAID use.

Outcome	Group A (Ayurvedic regimen)	Group B (standard therapy)	p value (between groups)
Composite symptom score - baseline	15.2±3.4	15.0±3.5	0.79
Composite symptom score - cycle 2	7.1±2.6	10.2±3.1	<0.001
Hours of limitation/absenteeism - baseline	16.4±6.2	15.9±6.0	0.72
Hours of limitation/absenteeism - cycle 2	6.8±4.1	10.9±5.2	<0.001
NSAID tablets per cycle - baseline	4.2±1.6	4.1±1.7	0.86
NSAID tablets per cycle - cycle 2	1.1±1.2	2.8±1.5	<0.001

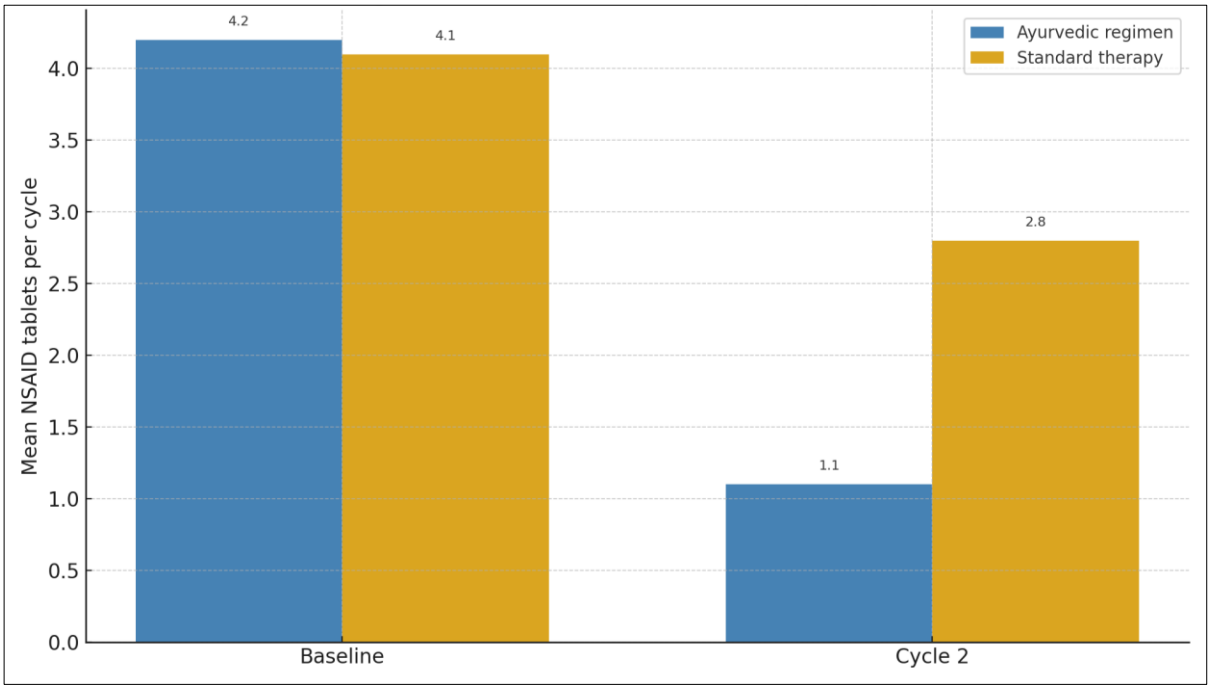

Fig 3: Mean number of rescue NSAID tablets used per cycle at baseline and at the second treatment cycle in both groups.

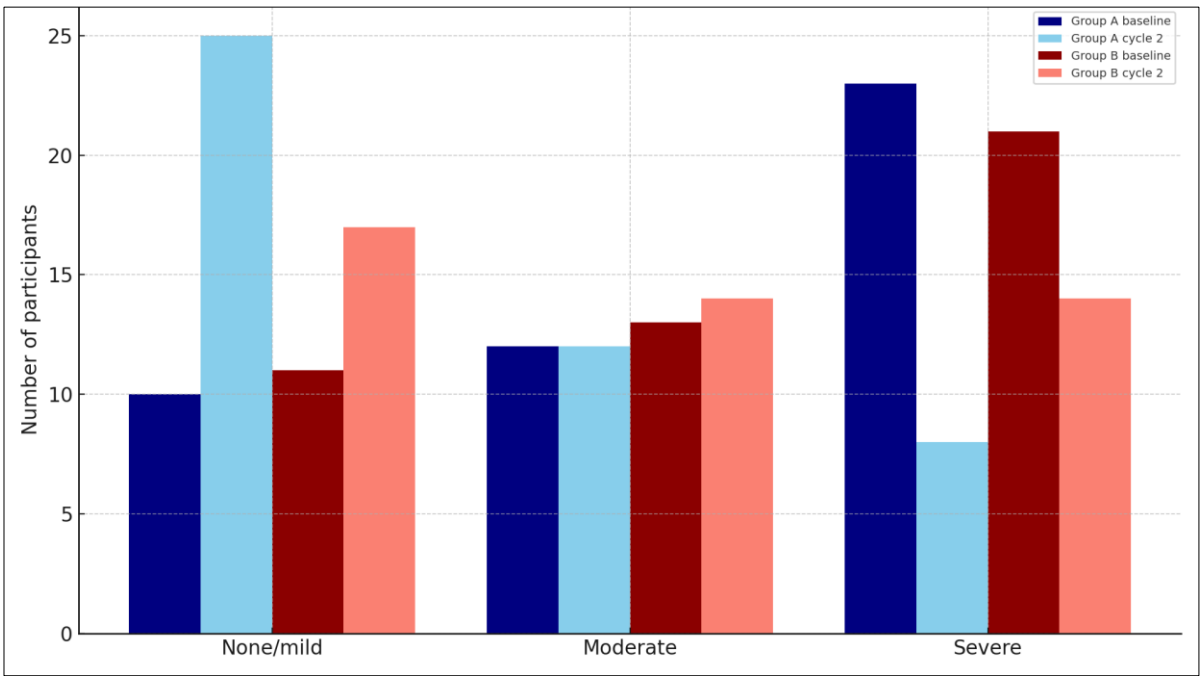

Fig 4: Distribution of participants by functional limitation category (none/mild, moderate, severe) at baseline and at the second treatment cycle in both groups.

Safety and tolerability

No serious adverse events were reported in either group during the study period. Mild gastrointestinal complaints (epigastric discomfort, acidity) were more frequently reported in the standard therapy group, consistent with known NSAID-related adverse effects [3, 14, 15]. In Group A, a small number of participants reported transient sensations of warmth or mild loose stools during the initial days of treatment, which subsided spontaneously or with minor dose adjustment; such effects have been previously noted with

certain Dipana-Pachana herbs but are generally self-limiting [8, 9, 12, 14].

Table 4: Adverse events profile in the Ayurvedic regimen and standard therapy groups.

Adverse event	Group A (n=45)	Group B (n=45)	p value
Any adverse event (%)	7 (15.6)	11 (24.4)	0.30
Gastric discomfort/acidity (%)	2 (4.4)	7 (15.6)	0.08
Nausea unrelated to menses (%)	1 (2.2)	2 (4.4)	0.56
Loose stools (%)	3 (6.7)	1 (2.2)	0.30
Headache unrelated to menses (%)	1 (2.2)	1 (2.2)	1.00
Serious adverse events	0	0	-

Overall, the Ayurvedic regimen was well tolerated and appeared safer with respect to gastrointestinal adverse effects than frequent NSAID use, in agreement with prior clinical experience and pharmacological data on the constituent herbs [7-9, 12, 14, 15]. The pattern of improvement in pain, associated symptoms, functional outcomes and reduced reliance on NSAIDs, against a backdrop of minimal adverse events, supports the potential role of a standardized Ayurvedic regimen as an effective and holistic therapeutic option in the management of primary dysmenorrhea (Kashta Artava) [1-15].

Discussion

In this randomized controlled trial, a standardized Ayurvedic regimen demonstrated superior efficacy to standard NSAID-based care in reducing pain intensity, associated symptoms, functional limitation, and rescue medication use among women with primary dysmenorrhea (Kashta Artava), with a favourable safety profile. These findings support the growing body of evidence that Ayurveda-based multimodal interventions can offer a clinically meaningful and holistic alternative or adjunct to conventional management of dysmenorrhea [4-9, 11-13]. The observed mean reduction of more than 4 points on the 10-cm VAS in the Ayurvedic group, and the significantly higher proportion of participants achieving ≥50% pain reduction compared with standard therapy, is particularly noteworthy in the context of global data showing that a large proportion of young women continue to experience moderate-severe pain despite analgesic use and often remain functionally impaired during menses [1-3].

The magnitude of pain relief and improvement in composite symptom scores seen in the Ayurvedic regimen group is broadly comparable to, or greater than, improvements reported in earlier single-arm and observational studies on Kashta Artava using Phala Taila Matra Basti, Vishwadi Kwatha, Vijayadi Vati, Kanyalauhadi Vati with Manjistha Churna and other Vata-shamaka, Shoolaprashamana and Artava-modulating formulations [7-9, 11, 12]. For example, trials of Matra Basti and internal formulations have reported substantial reduction in pain intensity and duration over 2-3 cycles, but many lacked a parallel control group or rigorous allocation concealment [7-9, 11]. The present study extends this evidence by employing a prospective randomized controlled design with intention-to-treat analysis and an active comparator (standard NSAID-based therapy), thereby addressing important methodological lacunae in earlier Ayurvedic dysmenorrhea research [7-13]. The finding that nearly 70% of women in the Ayurvedic group achieved ≥50% pain reduction, compared with about 38% in the standard therapy group, suggests that the regimen may not only match but surpass conventional care in a substantial subset of patients, while simultaneously reducing reliance on NSAIDs.

From an Ayurvedic pathophysiological perspective, primary dysmenorrhea corresponds closely to Kashta Artava, in which vitiated Apana Vayu, often accompanied by Agni-dushti, Ama formation and Srotorodha, leads to painful expulsion of Artava and multiple systemic manifestations [4-6, 10, 11]. The present regimen was intentionally designed to address these core derangements using Vata-shamaka, Shoolaprashamana, Dipana-Pachana and Artava-janana measures, together with counselling on Rajaswala Paricharya and lifestyle triggers [4-6, 10-13]. The greater improvement in low back pain, fatigue and gastrointestinal symptoms in the Ayurvedic group is consistent with this multidimensional approach, which seeks not only to suppress pain but to normalize Vata, clear Ama, support Agni, and correct faulty dietary and behavioural patterns that have been implicated as etiological factors in Kashta Artava [4-6, 10, 11]. The shift from “severe” to “none/mild” functional limitation in a large proportion of participants in the Ayurvedic group mirrors the emphasis in classical texts on restoring Yathochita Karma (usual daily activities) and not merely achieving symptomatic pain relief [4-6].

The reduction in rescue NSAID use is another clinically important finding. Long-term or frequent use of NSAIDs is associated with gastrointestinal, renal and neurological adverse effects, and is a concern particularly in adolescents and young women who may use these agents cyclically for many years [3, 14, 15]. In the present study, the Ayurvedic regimen led to an approximately 74% reduction in mean NSAID tablets per cycle, compared with about 32% in the standard therapy group. This suggests that integrating Ayurvedic interventions can potentially decrease drug burden and related risks without compromising symptom control. This is congruent with pharmacological and clinical data on ginger (Shunthi) and similar herbs, which have demonstrated analgesic and anti-inflammatory effects via partial inhibition of cyclo-oxygenase and prostaglandin synthesis, mechanisms relevant to dysmenorrhea [8, 9, 14]. Furthermore, the generally benign adverse-event profile observed in the Ayurvedic group, with only a few self-limiting gastrointestinal symptoms, supports the overall safety of such regimens when administered under supervision, as also suggested in prior trials and narrative reviews [7-9, 12, 14].

The consistency of our findings with previous etiological and clinical observations further enhances their plausibility. The predominance of Vata-Pitta Prakriti and the role of sedentary lifestyle, irregular diet and stress seen in earlier etiological studies of Kashta Artava [10, 11, 13] are reflected in the baseline characteristics of the present cohort, reinforcing the relevance of pathya-apathya counselling and Aharaj Rajaswalacharya-based dietary regulation as integral

components of management [4-6, 10, 11, 13]. A recent pilot study showed that dietary and lifestyle-based Rajaswala Paricharya alone could significantly reduce dysmenorrhea scores [13], and the present results suggest that combining such measures with targeted internal formulations may further enhance outcomes. In this sense, the trial aligns with a growing movement towards comprehensive, lifestyle-inclusive care in reproductive health, moving beyond a narrow pharmacologic focus [1-3, 4-6, 10-13].

At the same time, it is important to interpret the results in light of certain limitations. First, although the sample size was adequate to detect a clinically meaningful difference in VAS scores, the study was conducted at a single tertiary Ayurveda teaching hospital, which may limit generalizability to other settings and populations. Multi-centric trials across diverse regions and practice contexts are needed to confirm the reproducibility of these findings [1-3, 7-13]. Second, the study design used an open-label approach due to the inherent difficulties in blinding complex Ayurvedic regimens and lifestyle advice; this may have introduced performance and expectation bias, although the use of standardized, validated outcome measures and objective indices such as rescue NSAID consumption partially mitigates this concern [1-3, 7-9, 11-13]. Third, the follow-up period was limited to two treatment cycles; longer-term studies are necessary to assess the sustainability of benefits, potential cumulative effects, and any late-emerging adverse events [3, 7-9, 11-15].

Another consideration is that the comparator arm received standard NSAID-based therapy rather than a placebo or sham intervention. While this design enhances ethical acceptability and clinical relevance, it may underestimate the full effect size of the Ayurvedic regimen versus no active analgesic. Conversely, some components of the Ayurvedic regimen (e.g. lifestyle counselling, greater patient-practitioner interaction) could have non-specific benefits that are difficult to fully control for and may not be solely attributable to pharmacodynamic actions of the herbs [4-6, 10-13]. Future research could consider factorial or stepped-care designs that separately examine the effects of internal formulations, Panchakarma procedures, and structured Aharaj/Viharaj regimens on primary dysmenorrhea [4-9, 11-13].

Despite these limitations, the present study has several strengths, including clearly defined inclusion and exclusion criteria to ensure true primary dysmenorrhea [1-3, 15], explicit alignment of Ayurvedic diagnosis with classical descriptions of Kashta Artava [4-6, 10, 11], standardized dosing and timing of the regimen, active comparison with standard care, intention-to-treat analysis, and a multidimensional outcome framework encompassing pain, symptom burden, functional limitation and drug utilization [1-3, 7-13]. It also begins to bridge the conceptual framework of Ayurveda with contemporary understandings of dysmenorrhea, where uterine hypercontractility and elevated prostaglandins are central, and where non-pharmacological and complementary strategies are increasingly sought by patients concerned about long-term drug use [1-3, 8, 14, 15].

In summary, this trial suggests that a carefully designed Ayurvedic regimen, grounded in the principles of Vata-shamana, Shoolaprashamana, Dipana-Pachana and Artava-janana and supported by appropriate dietary and lifestyle counselling, can offer superior clinical benefits to standard NSAID-based therapy alone in primary dysmenorrhea (Kashta Artava), with meaningful reductions in pain, associated symptoms, functional impairment and rescue analgesic use, and with good tolerability [4-9, 11-15]. These findings justify further larger, multi-centric randomized trials and mechanistic studies to elucidate the biochemical and neuroendocrine pathways underlying the observed benefits, as well as health-economic analyses to assess the potential impact of integrating such regimens into routine gynecological and adolescent health services [1-3, 7-9, 11-15].

Conclusion

The present randomized controlled trial demonstrates that a standardized Ayurvedic regimen can offer clinically meaningful, multidimensional benefits in the management of primary dysmenorrhea (Kashta Artava), surpassing standard NSAID-based therapy alone in reducing menstrual pain, associated symptoms, functional limitation and reliance on rescue analgesics, while remaining well tolerated and safe. The substantial decline in pain scores, the high proportion of women achieving marked pain reduction, and the significant improvement in daily functioning suggest that addressing the condition through Vata-shamana, Shoolaprashamana, Dipana-Pachana and Artava-janana principles, combined with appropriate dietary and lifestyle measures, can correct deeper pathophysiological imbalances rather than simply suppress symptoms for a short duration. These findings support the view that primary dysmenorrhea in young women should be managed holistically, with careful attention to menstrual behaviour, diet, sleep, physical activity and stress, instead of relying exclusively on cyclical analgesic intake over many years. In practical terms, clinicians working in both Ayurvedic and integrative settings may consider adopting a structured protocol that starts a few days before the expected onset of menstruation and continues through the initial days of bleeding, using proven formulations with antispasmodic and anti-inflammatory potential, accompanied by clear guidance on avoiding excessive cold, heavy or junk foods, irregular meal timings and erratic sleep patterns. Routine counselling on Rajaswala Paricharya and menstrual self-care practices should be integrated into adolescent health and gynaecology clinics, ensuring that young women understand the role of diet, hydration, gentle movement, local heat application and adequate rest in modulating pain and systemic symptoms. At the same time, NSAIDs can be retained as rescue medication for breakthrough pain, but their use should be carefully monitored, with the explicit goal of progressive reduction as the Ayurvedic regimen begins to exert its effect. For policy makers and programme planners, the results highlight the potential value of incorporating evidence-based Ayurvedic dysmenorrhea management modules into school and college health programmes, adolescent-friendly clinics and primary care packages, thereby addressing a major but often neglected cause of absenteeism and reduced academic performance. Future implementation efforts should prioritise training of practitioners in standardized protocols, developing user-friendly patient education materials, and creating simple monitoring tools (such as menstrual pain and function diaries) to track outcomes over time. Finally, while these findings are encouraging, they should catalyse further multi-centric, longer-term research to refine dosage schedules, identify the most effective formulation combinations, and explore biological mechanisms, so that integrative management of primary dysmenorrhea can be offered with

growing confidence, transparency and reproducibility across diverse clinical settings.

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