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Research Article

Treatment of Dysmenorrhea

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A Prospective, Open-label Non-Randomized Clinical Trial to evaluate the Safety and Efficacy of M2-Tone Tablet in Treatment of Dysmenorrhea

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Background: Dysmenorrhea is a common gynecological condition affecting women of reproductive age, characterized by painful menstrual cramps that can significantly impact daily activities and quality of life. Managing dysmenorrhea requires a personalized approach that often combines lifestyle changes, pain management strategies, and pharmaceutical treatments. While NSAIDs and hormonal therapies remain standard treatments, alternative options such as herbal formulations are being explored. M2-Tone Tablet, a polyherbal product by Charak Pharma Pvt. Ltd., was evaluated for efficacy and safety in a Phase 3, open-label, multi-centric clinical trial involving 300 women (aged 18–45) diagnosed with dysmenorrhea.

Materials and Method: This phase 3, prospective, open-label, multi-centric clinical trial aimed to evaluate the clinical efficacy and safety of M2-Tone Tablet, a polyherbal formulation, in managing pelvic pain and dysmenorrhea in 300 women aged 18–45 years diagnosed with dysmenorrhea.

Observation: This clinical trial evaluated the efficacy of M2-Tone Tablet in managing dysmenorrhea over a 90-day period using a verbal multi-dimensional scoring system. A total of 300 participants were assessed for working ability, systemic symptoms, and analgesic use. At baseline, Grade 3 severity was reported by 48% (working ability), 42% (systemic symptoms), and 68% (analgesic use). Post-treatment, these rates declined significantly by 75%, 78.6%, and 73.5%, respectively ($p < 0.001$). Haematological parameters showed improvement, with haemoglobin increasing from 10.58 ± 2.07 g/dL to 11.47 ± 2.17 g/dL. Menstrual indicators such as clot passage, bleeding duration, and pad usage also reduced. Pain severity, measured on the Visual Analog Scale, improved by 31.2%, with notable relief in menstrual cramps (50.8%), headache (55%), and gastrointestinal symptoms (≥60%).

Result: Overall, M2-Tone tablets demonstrated significant efficacy in managing dysmenorrhea, enhancing functional capacity and reducing analgesic dependence. No adverse events were reported, reinforcing its safety profile as a non-hormonal, herbal alternative for symptom relief.

Keywords: Dysmenorrhea, M2-Tone Tablet, Herbal medicine, Menstrual cramps, Polyherbal formulation, Clinical trial, Pain management, Menstrual health

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Introduction

Dysmenorrhea is the most common symptom among menstrual complaints and represents a significant health burden, particularly in developing countries. It is more prevalent than other forms of chronic pelvic pain, such as dyspareunia or non-cyclical pelvic pain, and affects a substantial number of women globally. Studies show that between 67% to 90% of women aged 17–24 experience dysmenorrhea, with some studies reporting up to 93% prevalence in teenage girls. In adult women, prevalence rates vary widely, from 15% to 75%, with severe pain that limits daily activities affecting approximately 7% to 15%. However, a study in adolescents and young adults under 26 found that 41% of participants had daily activity limitations due to dysmenorrhea.**[1]**

Symptomatology: Primary dysmenorrhea (PD) results from increased prostaglandin production in the endometrial lining, triggering uterine contractions and menstrual pain. This process is driven by hormonal fluctuations, particularly the post-ovulatory decline in progesterone. Symptoms, including lower abdominal pain, backache, nausea, fatigue, and gastrointestinal discomfort, typically last 8 to 72 hours from menstruation onset. Psychological symptoms like anxiety and depression further impact quality of life (Table 1). NSAIDs and hormonal contraceptives are standard treatments, as they inhibit prostaglandin production.**[2]**

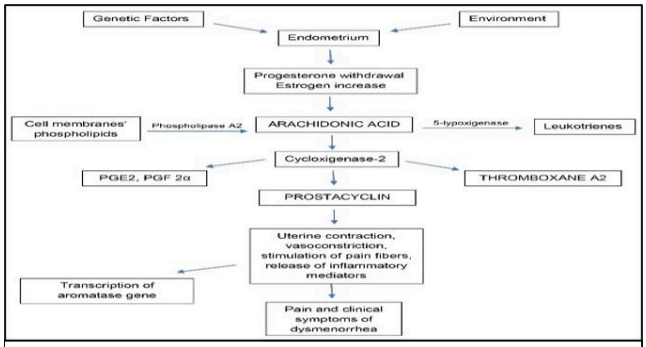
Severity correlates with factors such as age, BMI, smoking, early menarche, nulliparity, heavy menstrual flow, family history, and mental health conditions like depression and stress. Although other lifestyle factors have been studied, their association with dysmenorrhea remains inconclusive. Understanding these risk factors is essential for optimizing management and improving patient outcomes. This condition, while common, can be debilitating, and its management requires a thorough understanding of these risk factors in order to improve treatment outcomes and quality of life for those affected.**[3]**

Pathogenesis: Primary dysmenorrhea (PD), the most common menstrual pain in adolescents, typically arises about six months post-menarche due to anovulatory cycles and elevated prostaglandin (PG) levels, particularly PGF2α, which induce uterine contractions and pain.

Its multifactorial etiology includes genetic predisposition, as seen in monozygotic twins, along with risk factors like smoking, anxiety, and low socio-economic status. In contrast, secondary dysmenorrhea stems from conditions such as endometriosis and fibroids. The pathophysiology of both types involves hormonal fluctuations, inflammatory mediators like PGs and leukotrienes, and genetic influences, highlighting the complexity of menstrual pain management.**[4,5]**

Table 1: Risk factors and symptoms commonly reported for dysmenorrhea.

Risk factors	Symptoms	
Low BMI	More Frequent	Less Frequent
Nulli-parity, early menarche	Cramps	Loss of appetite
Positive family history	Nausea	Dyschezia
Tobacco habit and sedentary lifestyle	Vomiting	Genito-urinary symptoms
Depression, stress, anxiety	Headaches	Facial blemish
High caffeine consumption, insufficient intake of polyunsaturated fatty acids	Irritability	Flushing
Presence of periodic or chronic pain syndromes	Abdominal pain	Sleeplessness
Autoimmune disorders	Backaches & leg aches	Dizziness
	Depression	General aching
	Dyspareunia	Weakness



Schematic representation of the main mechanisms occurring in the uterus which dysregulation is shown and/or thought to be associated with primary dysmenorrhea. PGE2, prostaglandin E2; PGF2α, prostaglandin F2α.

Conventional Treatment: Treatment strategies for Primary Dysmenorrhea (PD) focus on pain relief and quality-of-life improvement by targeting prostaglandin inhibition, uterine tone reduction, and pain perception.

Options include pharmacological (e.g., NSAIDs, hormonal contraceptives) and non-pharmacological approaches, requiring individualized selection through shared decision-making.

While NSAIDs are commonly used, their efficacy is often limited by gastrointestinal side effects, impacting adherence. Optimal timing of NSAID administration is crucial, with pre-emptive use before COX-2 activation ensuring effective prostaglandin suppression, whereas delayed intake results in suboptimal inhibition and gradual pain relief.

In response to these challenges, herbal alternatives have gained increasing attention as potential solutions for managing dysmenorrhea. Herbs such as Saraca ashoka, Asparagus racemosus, symplocos racemose, Zingiber officinale These herbs have long been recognized in traditional medicine for their efficacy in alleviating menstrual pain and discomfort.

Saraca ashoka has uterine tonic effects and helps regulate menstrual cycles, Asparagus racemosus supports hormonal equilibrium and mitigates cramping, symplocos racemose possesses anti-inflammatory and astringent properties that reduce uterine inflammation, and Zingiber officinale has well-documented anti-inflammatory and analgesic effects. Many more such herbs help in easing out the pain and symptoms of dysmenorrhea.

In the present study, M2-Tone Tablet, a polyherbal formulation, manufactured by Charak Pharma Pvt. Ltd. was studied for its efficacy and safety in patients with dysmenorrhea. The formulation has been standardized after formulating SOPs along with acute toxicity study. A total of 300 patients were studied.

Materials and Methods

Study Goals and Objectives: The main objective of the study was to evaluate clinical efficacy of M2-Tone Tablet on dysmenorrhea. Further, the study also observed clinical safety of M2-Tone Tablet on dysmenorrhea.

Study Design: A non-randomized, phase 3, prospective, open label, multi-centric clinical trial in women diagnosed with dysmenorrhea was planned following required GCP guidelines. A total of 300 women were included in the study diagnosed with dysmenorrhea

Inclusion Criteria

The inclusion criteria for this clinical trial focused on women with:

1. Age 18–45 years with a confirmed diagnosis of primary dysmenorrhea, established through clinical evaluation.
2. Regular menstrual cycles (every 21–35 days) for at least six months prior to enrolment
3. Moderate to severe menstrual pain, measured using a standardized pain scale (e.g., Visual Analog Scale [VAS] score ≥4)
4. Good general health and ability to provide informed consent
5. Willingness to comply with all study requirements, including attending study visits and adhering to treatment protocols
6. Adequate understanding of study procedures and effective communication with study staff
7. Availability for the entire duration of the study period

Exclusion Criteria

Participants were excluded if they had any of the following:

1. Chronic pelvic pain unrelated to dysmenorrhea
2. Use of hormonal treatments (e.g., oral contraceptives) within the past three months
3. Significant systemic conditions such as hypertension, diabetes, or systemic disorders Pregnancy or lactation
4. Recent surgeries
5. Substance abuse
6. Psychiatric disorders
7. Unstable medical conditions
8. Gynaecological conditions like endometriosis, uterine fibroids, adenomyosis, or hormonal imbalances (e.g., PCOS)
9. Chronic pain disorders (e.g., fibromyalgia), allergies to the study drugs, or medications interfering with pain perception.
10. Participation in recent clinical trials or those with conditions potentially confounding results were excluded, ensuring reliable & consistent trial outcomes.

Methodology

Eligible participants who agreed to participate in the clinical study, after thorough explanation of procedures, were asked to sign a Patient Consent Form. During the initial visit (baseline at day 0), participants received a Patient Information Sheet in their preferred language. The attending physician completed a Case Record Form (CRF) that included the participant's complete medical history and relevant personal details.

Additionally, patients completed general assessment parameter like pain levels (pelvic inflammation, dysmenorrhea, dyspareunia) using the Visual Analogue Scale (VAS), analgesic use, patient satisfaction, and overall quality of life. A non-randomized, phase 3, prospective, open label, multi-centric clinical trial in 300 patients diagnosed with dysmenorrhea was planned following required GCP guidelines. After careful selection in terms of the eligibility criteria, screened subjects willing to enroll after explaining the clinical study procedure were requested to sign the Patient Consent Form.

At baseline visit at day 0, Patient information sheet was provided to each subject in their language of preference. Case record form (CRF) was filled by the attending physician with complete medical history and required personal details of the subject at the start of the study.

A thorough physical examination and necessary laboratory investigations were carried out before drug administration and after completion of treatment. Safety and efficacy evaluation of patients' clinical response to treatment was monitored at baseline and at end of 3 months.

All data were carefully entered in the Case Record Form provided. Side-effects were closely monitored in all patients. All adverse events were recorded by the investigator, and rated for severity and relationship to the study medication.

Clinical assessments

The patients were evaluated at baseline, after 45 & 90 days of treatment. Efficacy was measured in terms of the verbal multidimensional scoring system for assessment of severity of dysmenorrhea with parameters such as working ability, systemic symptoms & Analgesics. Further, visual analog for pain, menstrual cramps, headache, diarrhea, faint, mood changes, tiredness, nausea and vomiting during menses.

Intervention

M2-Tone Tablet, polyherbal formulation, manufactured by Charak Pharma Pvt. Ltd. was studied for its efficacy & safety in patients with dysmenorrhea, in dose of two tablet twice day after meals with water started on 1st day of menstrual cycle & given for 3 months. M2 Tone Tablets contain herbs such as *Ashoka, Lodhra, Haritaki, Vasa, Vata, Devdaru, Kokilaksh, Shatavari* & *Amalaki*.

Table 2: The verbal multidimensional scoring system for assessment of severity of dysmenorrhea[6]

Grade	Working ability	Systemic symptoms	Analgesics
Grade 0: Menstruation is not painful and daily activity is unaffected	Unaffected	None	Not required
Grade 1: Menstruation is painful but seldom inhibits the woman normal activity. Analgesics are seldom required. Mild pain	Rarely affected	None	Rarely required
Grade 2: Daily activity affected. Analgesics required and give relief so that absence from work or school is unusual. Moderate pain	Moderately affected	Few	Required
Grade 3: Activity clearly inhibited. Poor effect of analgesics. Vegetative, symptoms, e.g., headache, tiredness, nausea, vomiting, and diarrhea. Severe pain	Clearly inhibited	Apparent	Poor effect

Observations

Table 3: Observations of the verbal multi-dimensional scoring system for assessment of severity of dysmenorrhea.

Observation	Category	Working Ability	Systemic Symptoms	Analgesic Use
Before Treatment	Grade 3	48% (144/300)	42% (126/300)	68% (204/300)
	Grade 2	42% (126/300)	48% (144/300)	31% (93/300)
	Grade 1	9% (27/300)	9% (27/300)	1% (3/300)
	Grade 0	1% (3/300)	1% (3/300)	0% (0/300)
	Mean ± SD	2.5 ± 0.7	2.3 ± 0.8	2.8 ± 0.5
After 45 Days of Treatment	Grade 3	35% (105/300)	30% (90/300)	50% (150/300)
	Grade 2	40% (120/300)	45% (135/300)	35% (105/300)
	Grade 1	20% (60/300)	20% (60/300)	12% (36/300)
	Grade 0	5% (15/300)	5% (15/300)	3% (9/300)
	Mean ± SD	2.1 ± 0.6	1.9 ± 0.7	2.4 ± 0.6

After 90 Days of Treatment	Grade 3	12% (36/300)	9% (27/300)	18% (54/300)
	Grade 2	28% (84/300)	32% (96/300)	48% (144/300)
	Grade 1	49% (147/300)	48% (144/300)	31% (93/300)
	Grade 0	11% (33/300)	11% (33/300)	3% (9/300)
	Mean ± SD	1.3 ± 0.6	1.2 ± 0.7	1.5 ± 0.6
	p-value	<0.001	<0.001	<0.001

Table 4: Effect of M2 Tone Tablets on Dysmenorrhea (Mean ± SD)

SN	Parameter	Before Treatment	After 45 Days of Treatment	After 90 Days of Treatment
1.	Hemoglobin (Hb%)	10.58 ± 2.07	11.02 ± 2.12	11.47 ± 2.17
2.	Passage of Clots (No.)	2.26 ± 0.54	1.80 ± 0.50	1.33 ± 0.47
3.	Duration of Bleeding (days)	6.97 ± 1.55	5.12 ± 1.20	3.92 ± 0.95
4.	Number of Pads Used	5.84 ± 1.47	4.45 ± 1.12	3.04 ± 0.88
5.	Severity of Pain During Menses (VAS, 0–100)	59.68 ± 22.47	50.36 ± 18.90	41.05 ± 16.20

Table 5: Changes in the mean symptom scores after 3 months of therapy

SN	Parameters	Before Treatment (Mean ± SD)	After 45 Days of Treatment (Mean ± SD)	After 90 Days of Treatment (Mean ± SD)	Percentage Improvement
1.	Pain (VAS)	59.68 ± 22.47	50.20 ± 18.75	41.05 ± 16.20	31.2% Reduction
2.	Menstrual Cramps	6.5 ± 1.5	4.8 ± 1.3	3.2 ± 1.1	50.8% Reduction
3.	Headache	4.0 ± 1.2	3.5 ± 1.1	3.2 ± 1.1	55.0% Reduction
4.	Diarrhea	3.5 ± 1.3	2.6 ± 1.0	1.8 ± 0.8	60.0% Reduction
5.	Fainting	2.5 ± 0.9	2.0 ± 0.8	1.4 ± 0.9	68.0% Reduction
6.	Mood Changes	5.0 ± 1.7	2.8 ± 1.0	0.8 ± 0.5	56.0% Reduction
7.	Tiredness	5.8 ± 1.6	4.0 ± 1.2	2.2 ± 1.0	56.9% Reduction
8.	Nausea	3.2 ± 1.4	2.9 ± 1.2	2.5 ± 1.1	65.6% Reduction
9.	Vomiting during Menses	2.8 ± 1.3	1.9 ± 0.9	1.1 ± 0.7	67.9% Reduction

Results

The efficacy of M2-Tone Tablet in managing dysmenorrhea was evaluated using a verbal multi-dimensional scoring system, assessing working ability, systemic symptoms, and analgesic use over a 90-day period. M2 Tone Tablets significantly reduced the severity of dysmenorrhea across all evaluated parameters, indicating improvements in working ability, systemic symptoms, and reduced reliance on analgesics. The changes were statistically significant, with p-values < 0.001 for all metrics.

At baseline, a substantial proportion of participants reported severe dysmenorrhea-related impairments. Grade 3 working ability restrictions were observed in 48% (144/300) of participants, systemic symptoms in 42% (126/300), and frequent analgesic use in 68% (204/300). Grade 2 symptoms were also prevalent, affecting 42% (126/300) for working ability, 48% (144/300) for systemic symptoms, and 31% (93/300) for analgesic use. Only a minimal number of participants were in Grade 1 or Grade 0 categories. The mean ± SD scores were 2.5 ± 0.7 for working ability, 2.3 ± 0.8 for systemic symptoms, and 2.8 ± 0.5 for analgesic use, indicating a high symptom burden at baseline.

After 45 days of M2-Tone administration, a moderate but statistically significant reduction in symptom severity was observed across all parameters. The proportion of Grade 3 cases declined to 35% (105/300) for working ability, 30% (90/300) for systemic symptoms, and 50% (150/300) for analgesic use. Correspondingly, Grade 1 and Grade 0 cases increased, indicating a shift towards milder symptoms.

The mean ± SD scores decreased to 2.1 ± 0.6 (working ability), 1.9 ± 0.7 (systemic symptoms), and 2.4 ± 0.6 (analgesic use), reflecting a reduction in symptom severity. The relative percentage decrease in Grade 3 cases compared to baseline was 27.1% for working ability, 28.6% for systemic symptoms, and 26.5% for analgesic use.

By 90 days, symptom relief was more pronounced, with a substantial decline in Grade 3 cases. The prevalence of Grade 3 cases dropped to 12% (36/300) for working ability (a 75% reduction from baseline), 9% (27/300) for systemic symptoms (a 78.6% reduction), and 18% (54/300) for analgesic use (a 73.5% reduction). Simultaneously, Grade 1 cases significantly increased to 49% (147/300) for working ability, 48% (144/300) for systemic symptoms, and 31% (93/300) for analgesic use.

The proportion of participants who experienced complete symptom relief (Grade 0) also increased, reaching 11% (33/300) for working ability, 11% (33/300) for systemic symptoms, and 3% (9/300) for analgesic use.

The mean ± SD scores at 90 days further decreased to 1.3 ± 0.6 (working ability), 1.2 ± 0.7 (systemic symptoms), and 1.5 ± 0.6 (analgesic use), demonstrating a significant improvement compared to baseline. The percentage reductions in mean scores from baseline were 48% for working ability, 47.8% for systemic symptoms, and 46.4% for analgesic use, reflecting a consistent pattern of improvement.

The p-values for all parameters were <0.001, indicating that the observed improvements were highly statistically significant. The steady decline in symptom severity, coupled with the reduction in analgesic dependency, highlights the sustained therapeutic efficacy of M2-Tone Tablet over 90 days. These results suggest that M2-Tone could be an effective intervention for managing dysmenorrhea, improving functional ability, reducing systemic symptoms, and minimizing the need for analgesic consumption. The findings are clinically relevant as they support a non-hormonal, herbal-based approach to dysmenorrhea management, potentially offering a safer alternative to conventional analgesic therapy.

The effect of M2-Tone Tablets on dysmenorrhea was assessed through various clinical parameters over a 90-day treatment period. The results, as presented in Table 4, demonstrate statistically and clinically significant improvements across all measured outcomes. Haemoglobin (Hb%) levels showed a progressive increase from 10.58 ± 2.07 g/dL before treatment to 11.47 ± 2.17 g/dL after 90 days, indicating an improvement in overall haematological health, likely due to better menstrual regulation and reduced blood loss. A marked reduction in passage of clots was observed, with the mean count decreasing from 2.26 ± 0.54 to 1.33 ± 0.47 by the end of the study, suggesting a positive impact on coagulation and uterine health. Duration of bleeding significantly declined from 6.97 ± 1.55 days to 3.92 ± 0.95 days, demonstrating the tablet's efficacy in normalizing menstrual flow. Additionally, the number of pads used per cycle decreased from 5.84 ± 1.47 to 3.04 ± 0.88, reflecting reduced menstrual flow and improved cycle regulation.

The severity of pain during menses, measured using the Visual Analog Scale (VAS, 0–100), showed a substantial decrease from 59.68 ± 22.47 to 41.05 ± 16.20, indicating a significant reduction in dysmenorrhea symptoms. Collectively, these findings suggest that M2-Tone Tablets effectively alleviate dysmenorrhea by improving haematological parameters, reducing excessive bleeding, and alleviating pain severity, thereby enhancing the overall quality of life for patients. Further statistical validation and subgroup analysis can strengthen these observations and confirm the therapeutic potential of M2-Tone in menstrual health management.

Pain, measured via the Visual Analog Scale (VAS), demonstrated a significant reduction from 59.68 ± 22.47 at baseline to 50.20 ± 18.75 at 45 days and further to 41.05 ± 16.20 at 90 days, indicating a 31.2% overall improvement. Menstrual cramps showed a pronounced 50.8% reduction (from 6.5 ± 1.5 to 3.2 ± 1.1), suggesting a strong therapeutic effect. Headache scores also declined significantly (55.0% reduction), supporting the analgesic potential of the intervention. Gastro-intestinal symptoms such as diarrhoea (60.0% reduction) and nausea (65.6% reduction) showed substantial improvement, while vomiting during menses experienced a 67.9% decline. The therapy also positively impacted neurological and psychological symptoms, with fainting episodes decreasing by 68.0%, mood changes by 56.0%, and tiredness by 56.9%.

Overall, the treatment exhibited statistically and clinically relevant improvements in all evaluated parameters, with a marked reduction in symptom severity over time. These findings suggest that M2-Tone Tablet may be an effective intervention for managing dysmenorrhea and associated menstrual discomfort. Further statistical validation with inferential tests (e.g., paired t-test, ANOVA) would help establish the significance of these observations. These findings indicate a substantial alleviation of symptoms across all parameters, highlighting the therapy’s efficacy in improving patient outcomes.

Discussion

The initial treatment for suspected dysmenorrhea is often empirical, typically involving nonsteroidal anti-inflammatory drugs (NSAIDs) or hormonal therapies aimed at modulating the menstrual cycle.

While NSAIDs provide short-term relief by targeting pain and inflammation, they do not address the underlying pathophysiology of dysmenorrhea, including inflammation, altered immune response, oxidative stress, and uterine muscle contractions. Additionally, NSAIDs may be limited by side effects and reduced long-term efficacy.

In contrast, a more holistic approach is offered by M2-Tone Tablet, a polyherbal Ayurvedic formulation specifically designed for the management of dysmenorrhea and chronic pelvic pain. Unlike NSAIDs, M2-Tone Tablet targets the root causes of menstrual disorders by addressing inflammation, hormonal imbalances, and uterine dysfunction. M2 Tone Tablets contain herbs such as *Ashoka, Lodhra, Haritaki, Vasa, Vata, Devdaru, Kokilaksh, Shatavari* and *Amalaki*, many of which have been traditionally recognized for their beneficial effects on menstrual health. These herbs work synergistically to regulate the menstrual cycle, reduce uterine inflammation, and support overall reproductive health, offering a more comprehensive solution to dysmenorrhea compared to NSAIDs.

Saraca indica, a plant revered in traditional medicine, has shown significant uterine and gynecological benefits. Its bark contains compounds such as epicatechin, catechin, and leucocyanidin, while its flowers and seeds are rich in fatty acids and flavonoids. Pharmacologically, *Saraca indica* demonstrates anti-menorrhagic and uterine tonic properties, effectively managing menstrual disorders such as menorrhagia, dysmenorrhea, and other uterine afflictions. The plant's aqueous and alcoholic extracts stimulate uterine contractions, akin to ergot, but without inducing tonic contractions. Its role as a uterine sedative and its estrogenic activity further emphasizes its importance in menstrual health. Additionally, it possesses anti-inflammatory, analgesic, and antioxidant properties, contributing to overall relief from menstrual pain and supporting reproductive health. The plant's multifaceted activities make it valuable for treating dysmenorrhea, menstrual irregularities, and related conditions without significant adverse effects.**[7]** *Lodhra* (*Symplocos racemosa*) is known for its diverse phytochemical composition, which includes flavonoids, phenols, tannins, saponins, glycosides, alkaloids, and triterpenoids. Key bioactive compounds like symplocoside, leucopelargonidin-3 glucoside, ellagic acid, rhamnetin 3-digalactoside, And alkaloids such as oturine and harmine, contribute to its medicinal properties. The ethanolic extract of *Lodhra* bark has been shown to be effective in treating female reproductive disorders, including dysmenorrhea, by modulating uterine function. The plant's anti-inflammatory, analgesic, and uterine tonic activities help alleviate menstrual pain and regulate menstrual cycles, making it beneficial for addressing menstrual discomfort and promoting uterine health.**[8]**

Shivlingi Beej (*Bryonia laciniosa*) is a potent uterine tonic known for its efficacy in treating dysmenorrhea. Its key phyto-constituents, including Punilic Acid, Goniothalamin, and Glucomannan, contribute to its anti-inflammatory, analgesic, and hormonal-balancing effects. These compounds help alleviate menstrual pain, reduce inflammation, and improve uterine and ovarian health. *Shivlingi Beej* also detoxifies the uterus and normalizes menstrual cycles, making it especially useful for women with light or absent menstrual flow. It is contraindicated in cases of heavy bleeding but offers significant relief for those with menstrual discomfort, hormonal imbalances, and associated emotional distress.**[9]**

Shatavari (*Asparagus racemosus*), a revered herb in traditional medicine, is highly effective in managing dysmenorrhea due to its uterine tonic properties. Rich in saponins like Shatvarins, sarsapogenin, and flavonoids such as quercetin and rutin, Shatavari helps in alleviating menstrual discomfort by regulating hormonal balance and improving uterine health. The saponins present in Shatavari inhibit oxytocic action on uterine musculature, thus maintaining normal uterine motility and preventing painful contractions associated with dysmenorrhea. Additionally, its antioxidant compounds like racemofuran and asparagamine A reduce oxidative stress, which is often contributing factor to menstrual pain. *Shatavari* also nourishes and strengthens uterine wall, supports follicular development, and improves ovarian function, making it holistic remedy for menstrual irregularities and painful periods. Its calming and anti-inflammatory effects further contribute to its efficacy in reducing severity of dysmenorrhea.**[10]** M2-Tone is comprehensive formulation for menstrual disorders. M2- Tone contains potent pro-estrogenic agents like *Saraca indica* and *Symplocos racemosa*, which correct estrogenic insufficiency and improve ovarian functions. M2- Tone maintains nutritional balance and improves endometrial health.

M2- Tone with help of herbs like *Withania somnifera* and *Nardostachys jatamansi* restores emotional balance by relieving anxiety and stress, which are the predisposing factors for menstrual irregularities and anovulation. *Mesua ferrea* improves the endocrinal function and restores hormonal balance. *Nardostachys jatamansi* also has antispasmodic and anxiolytic activity. *Shuddha Kasis* is a hematinic.

M2-Tone is a versatile therapeutic option offering benefits across various gynecological and fertility conditions. In young and adolescent patients with dysfunctional uterine bleeding (DUB), it helps restore the hypothalamic-pituitary-ovarian (H-P-O) axis, maintains endometrial integrity, normalizes menstrual flow, and regularizes menstrual cycles. For unexplained infertility, M2-TONE promotes timely ovulation by balancing the H-P-O axis, enhances the intra-uterine environment for conception and implantation, increases endometrial glycogen content, and supports normal endometrial proliferation. In an-ovulatory infertility, it complements Clomiphene citrate to improve conception rates by increasing endometrial thickness, vascularity, and receptivity, along with enhancing glycogen content. In assisted reproductive technology (ART) protocols, M2- Tone further improves endometrial thickness and receptivity, aiding successful implantation. These combined actions make it a valuable adjunct in reproductive and gynecological health.

Conclusion

The present study demonstrates that M2-Tone, a polyherbal formulation, is both effective and safe in managing the signs and symptoms of dysmenorrhea and its related complications. It significantly improves haemoglobin levels, reduces menstrual blood loss, shortens bleeding duration, and alleviates pain severity. These results highlight M2-Tone as promising and reliable option for managing dysmenorrhea and improving menstrual health.

Cost of Study

All medications required during 3 months of trial were provided by the sponsor. Radio-imaging and biochemical test mentioned were performed at the base line and the end of the trial. The cost for the same was sponsored by company. Charak Pharma Pvt. Ltd. reserves all rights over any publications of the study during the course and post completion.

Conflict of Interest

To avoid any conflict of interest, study was carried out under the unbiased supervision of Dr. Dukle's Vedic Healing Hospital, Vidnyanam Clinic, Chaudhari Clinic & Shree Vishwadhatri Ayurveda Clinic & Panchakarma Centre HCPs who are not associated with the sponsors.

References

1. Ju H, Jones M, Mishra G. The prevalence and risk factors of dysmenorrhea. Epidemiol Rev. 2014;36(1):104–13. *[Crossref][PubMed][Google Scholar]*

2. Itani R, Soubra L, Karout S, Rahme D, Karout L, Khojah HMJ. Primary dysmenorrhea: pathophysiology, diagnosis, and treatment updates. Korean J Fam Med. 2022;43(2):101–8. *[Crossref][PubMed][Google Scholar]*

3. Ju H, Jones M, Mishra G. The prevalence and risk factors of dysmenorrhea. Epidemiol Rev. 2014;36(1):104–13. *[Crossref][PubMed][Google Scholar]*

4. Francavilla R, Petraroli M, Messina G, Stanyevic B, Bellani AM, Esposito SMR, Street ME. Dysmenorrhea: epidemiology, causes and current state of the art for treatment. Clin Exp Obstet Gynecol. 2023;50(12):274. *[Crossref][PubMed][Google Scholar]*

5. Francavilla R, Petraroli M, Messina G, Stanyevic B, Bellani AM, Esposito SMR, Street ME. Dysmenorrhea: epidemiology, causes and current state of the art for treatment. Clin Exp Obstet Gynecol. 2023;50(12):274. *[Crossref][PubMed][Google Scholar]*

6. Andersch B, Milsom I. An epidemiologic study of young women with dysmenorrhea. Am J Obstet Gynecol. 1982;144(6):655–60. *[Crossref][PubMed][Google Scholar]*

7. Nyeem M. Ashoka (Saraca indica) as women friendly plant: a review. Int J Adv Educ Res. 2017;3:3–7. *[Crossref][PubMed][Google Scholar]*

8. Johnson T, Krishnakumar K, Dineshkumar B. Phyto-pharmacological review of Symplocos racemosa bark. J Bio Innov. 2018;7(4):611–7. *[Crossref][PubMed][Google Scholar]*

9. Singh J. Shivlingi Beej (Seeds) Benefits, Uses, Dosage & Side Effects [Internet]. Ayur Times; 2017 [cited 2025 Jul 7]. Available from: https://www. *ayurtimes.com/shivlingi-beej-seeds/ [Crossref] [PubMed][Google Scholar]*

10. Thakur S, Kaurav H, Chaudhary G. Shatavari (Asparagus racemosus) – the best female reproductive tonic. Int J Res Rev. 2021;8:73–84. *[Crossref][PubMed][Google Scholar]*