**RESEARCH PAPER**

# Local Heat Patch Application versus Oral Analgesics in Primary Dysmenorrhea: A Prospective Study Evaluating Pain Management Outcomes among Young Females in Rural South India

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## ABSTRACT

**Objective:** To evaluate comparative pain-management outcomes between local heat patch application and oral analgesics in the management of primary dysmenorrhea among medical students in rural South India, given the limited comparative evidence available despite widespread clinical use of heat therapy.

**Methods:** A prospective observational study was conducted among 161 female medical students aged 18–25 years with moderate-to-severe primary dysmenorrhea over two consecutive menstrual cycles (August 2023–January 2024). Participants were grouped according to their self-selected pain-management method: heat patch users (n=51), analgesic users (n=50), and non-users/control (n=60). Pain intensity was assessed using the Visual Analogue Scale (VAS) at baseline, 4-hour, and 8-hour intervals. Data were analyzed using repeated measures analysis of variance (ANOVA), paired t-tests, and one-way ANOVA, with significance set at $p<0.05$.

**Results:** Mean VAS score reductions were significantly greater in the heat patch group (6.74 and 6.40 in the first and second cycles, respectively) than in the analgesic group (3.88 and 3.51) and control group (1.53 and 0.88; $p<0.001$ for all between-group comparisons). Repeated measures ANOVA confirmed statistically significant temporal reductions for the heat patch group ($F=474.08$ and $F=712.11$, $p<0.001$). Baseline age, body mass index (BMI), and age at menarche did not differ significantly across groups.

**Conclusion:** Local heat patch application provides superior pain-relief efficacy compared with conventional oral analgesics in primary dysmenorrhea and merits consideration as an effective, non-pharmacological intervention for menstrual pain management.

**Keywords:** *Dysmenorrhea, Mefenamic Acid, Menstrual Cycle, Painful Menstruation, Pain Assessment, Pain Intensity, Visual Analogue Pain Scale*

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## INTRODUCTION

Dysmenorrhea, derived from ancient Greek terminology, represents a significant gynecological condition characterized by painful menstrual flow that substantially impacts women's quality of life and functional capacity. This pervasive clinical entity is systematically classified into primary and secondary dysmenorrhea, with primary dysmenorrhea defined as menstrual pain without discernible pelvic pathology, typically manifesting within the initial two years following menarche.[1] Secondary dysmenorrhea is distinguished by its association with underlying medical conditions such as pelvic inflammatory disease, establishing a critical diagnostic differentiation essential for precise clinical management and customized therapeutic interventions. [2]

The pathophysiological mechanisms underlying primary dysmenorrhea involve complex prostaglandin-mediated inflammatory cascades, resulting in enhanced myometrial contractility and subsequent ischemic pain. These biochemical processes create a multifaceted pain syndrome that extends beyond simple muscular discomfort, encompassing neurogenic pain transmission pathways and systemic inflammatory responses. Dysmenorrheal morbidity constitutes a substantial public health burden, serving as the primary etiology of absenteeism among adolescent females from educational

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and occupational responsibilities.[3,4] Despite contemporary understanding of dysmenorrhea's pathogenesis and therapeutic approaches, epidemiological data reveal concerning healthcare-seeking patterns. Studies demonstrate that only 19.3% to 28% of young women with dysmenorrhea pursue medical consultation, while self-medication practices predominate among teenagers, ranging from 35.1% to 60.9%. [5] These findings underscore critical gaps in healthcare accessibility, patient education, and awareness regarding evidence-based management strategies for menstrual discomfort.

Contemporary therapeutic approaches encompass diverse pharmacological and non-pharmacological interventions, including pharmacological agents, physical therapy modalities, complementary therapies, and lifestyle modifications.[6–10] Heat therapy, specifically, has demonstrated historical significance across various cultural contexts as a fundamental pain management strategy. Research indicates that heat application as a coping mechanism for dysmenorrhea ranges from 36.5% to 50% among affected populations.[11] Despite widespread clinical utilization, comprehensive comparative research examining structured heat patch applications versus conventional oral analgesic regimens remains limited in scope and methodological rigor, creating substantial knowledge gaps in evidence-based therapeutic recommendations for primary dysmenorrhea management in diverse healthcare contexts. The present study was carried out to observe and compare pain outcomes among medical students who self-selected local low-dose heat application, self-medication with oral analgesics, or no intervention, for managing dysmenorrheal pain.

## MATERIAL AND METHODS

### Study settings and duration

A prospective observational study was conducted among 161 female medical students at a teaching medical college in the Perambalur district, Tamil Nadu from August 2023 to January 2024.

### Sample Size Calculation and sampling method

According to Potur et al. study [11], considering the mean and standard deviation of pain score after 8 hours of analgesic use as 3.61 ± 3.08, mean and SD of pain score after 8 hours of heat patch use as 1.9 ± 2.39 at 95% confidence interval with 80% power, the sample size was calculated using the formula,

$$N = (Z_{1-\alpha/2} + Z_{1-\beta})^2 * 2 * \sigma^2 / (\mu_1 - \mu_2)^2$$

$Z_{1-\alpha/2}$ - two tailed probability for a 95% confidence interval = 1.96, $Z_{1-\beta}$ - two tailed probability for 80% power = 0.84, $\mu_1$ - mean of pain score after 8 hours of analgesic use = 3.61, $\mu_2$ - mean of pain score after 8 hours of heat patch use = 1.9, $\sigma$ - average SD of pain score after 8 hours of analgesic use & pain score after 8 hours of heat patch use = 2.74

The minimum sample size required per group was 40, giving a minimum overall sample size of 120; 161 participants were enrolled. Every eligible participant was included in a randomly generated list, and a referendum was conducted to determine group order: the heat patch group (HPG) was positioned third, the analgesic group (AG) second, and the control group (CG) first.

### Inclusion Criteria:

Medical students aged 18–25 years who were nulliparous; had a history of regular menstrual cycles (during the preceding 6 months) accompanied by moderate-to-severe pain (Visual Analogue Scale [VAS] score ≥5); had not used hormonal contraceptives; and had no systemic or chronic disease (e.g., diabetes, poor circulation, heart disease, rheumatoid arthritis) were included.

### Exclusion Criteria

Subjects with abdominal wall lesions, prior heat-patch use before the trial, concurrent use of complementary and alternative therapies, irregular periods, or febrile infectious disorders were excluded.

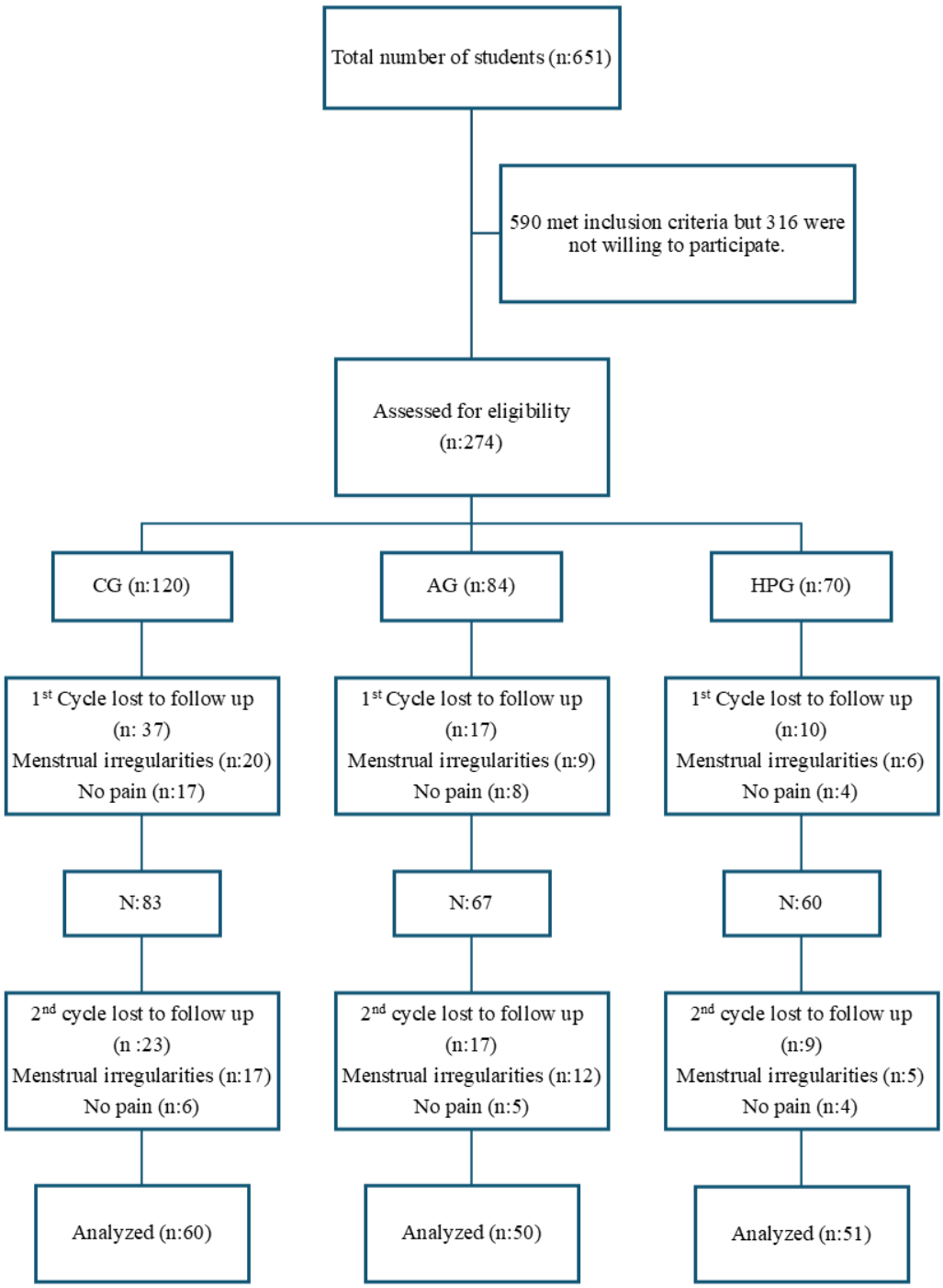


**Figure 1:** Participant selection flow diagram.

Figure 1 shows the flow diagram of participant selection. From a total population of 651 female medical students, 590 met the initial inclusion criteria, though 316 declined participation. The remaining 274 eligible participants were categorized into three groups based on self-reported pain-management practice, identified through convenience sampling: heat patch users (HPG, n=70), analgesic users (AG, n=84), and non-users (CG, n=120). During the first menstrual cycle, attrition occurred across all groups owing to loss to follow-up (HPG: 10, AG: 17, CG: 37), menstrual irregularities (HPG: 6, AG: 9, CG: 20), and absence of pain (HPG: 4, AG: 8, CG: 17), leaving 60, 67, and 83 participants, respectively. In the second cycle, further attrition occurred owing to loss to follow-up (HPG: 9, AG: 17, CG: 23), menstrual irregularities (HPG: 5, AG: 12, CG: 17), and absence of pain (HPG: 4, AG: 5, CG: 6). The final analysis included 51 participants in the heat patch group, 50 in the analgesic group, and 60 in the control group, totaling 161 participants who completed both cycles. Neither the heat patch group nor the control group was permitted to use analgesics during the study period.

**Stool tool**

**Primary dysmenorrhea assessment tool (PDAT)**

Participants were recruited through a structured Primary Dysmenorrhea Assessment Tool. This screening instrument, requiring approximately 15–20 minutes to complete, captured demographic, anthropometric, and reproductive health data, including age, marital status, contraceptive use, menstrual pattern over the preceding six months, irregular periods, dysfunctional uterine bleeding, pain intensity, gynecological conditions, and systemic or chronic disease. The form served as both a screening and exclusion tool, identifying eligible participants while documenting potential confounding factors.

**Visual Analogue Scale**

The VAS, a psychometric response scale, was used to evaluate dysmenorrheal pain. The vertical scale measures 0–10 cm: no pain at 0 cm, mild pain at 1–4 cm, moderate pain at 5 cm, and severe pain at 6–10 cm.[12]

**Pain assessment log**

This prospective instrument recorded pain-intensity fluctuations, functional status, and pain-management strategies at predetermined intervals: T1 (baseline), T2 (4-hour follow-up), and T3 (8-hour follow-up). All participants recorded baseline pain intensity on the VAS at T1, with subsequent recordings at T2 and T3.

**Health patch**

The study utilized commercially available disposable heat patches (Evereve; Universal Corporation Ltd, Palghar, Maharashtra, India) containing sodium, iron, coal, and water, which generate therapeutic heat through air-activated exothermic reactions. The proposed mechanism involves heat-induced vasodilation, enhanced localized blood circulation, and smooth-muscle relaxation, thereby diminishing pain perception. The patches provided consistent warming across a 180 cm² surface area, maintaining a constant temperature of 38.9°C (102.02°F). Patches required 15–30 minutes to reach optimal therapeutic temperature and sustained therapeutic warmth for 8 hours. Participants received standardized instructions for lower-abdominal application at menstruation onset, secured with undergarments for continuous contact across two consecutive menstrual cycles. [13]

**Ethical consideration:**

Ethics approval was obtained from the Institutional Ethics Committee for Human Subjects (Approval number: IECHS/IRCHS/414). The study was conducted in accordance with applicable ethical principles, and written informed consent was obtained from all participants.

**Statistical analysis**

Statistical analyses were performed using IBM SPSS Statistics, version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables (age, age at menarche, BMI) were expressed as mean ± SD, and categorical variables as frequencies and percentages. Between-group comparisons of demographic characteristics and baseline VAS scores were conducted using one-way ANOVA. Temporal evolution of pain scores across the three time points was analyzed using repeated measures ANOVA with Greenhouse-Geisser correction and post-hoc Bonferroni adjustment. Within-group comparisons of pain scores (pre- and post-observation) were performed using paired t-tests. All tests were two-tailed; significance was set at *$p<0.05$ and **$p<0.01$, and results are reported with 95% confidence intervals (CI).

**RESULTS**

Table 1 presents the baseline demographic and clinical characteristics across the three treatment groups. One-way ANOVA analysis revealed no statistically significant differences between the control, analgesic, and heat patch groups regarding age (F=1.855, p=0.16), BMI (F=0.003, p=0.997), and age at menarche (F=0.101, p=0.904), confirming baseline equivalence across intervention groups.

**Table 1:** Baseline Demographic and Clinical Characteristics across Treatment Groups

| Variables | Groups | n = 161 | Mean | Std. Deviation | F-statistic | p-value |
|---|---|---|---|---|---|---|
| Age (years) | Analgesic | 51 | 21.45 | 1.869 | 1.855 | 0.16 |
| | Control | 60 | 21.00 | 1.605 | | |
| | Heat Patch | 50 | 20.84 | 1.503 | | |
| Age at Menarche (years) | Analgesic | 51 | 12.76 | 1.226 | 0.101 | 0.904 |
| | Control | 60 | 12.68 | 1.157 | | |
| | Heat Patch | 50 | 12.66 | 1.349 | | |
| Body Mass Index ($Kg/m^2$) | Analgesic | 51 | 22.852 | 3.7861 | 0.003 | 0.997 |
| | Control | 60 | 22.907 | 3.7453 | | |
| | Heat Patch | 50 | 22.875 | 3.8406 | | |

SD = standard deviation. Statistical analysis was performed using one-way ANOVA; significance level set at $p<0.05$.

Table 2 demonstrates significant temporal pain reduction patterns across all treatment groups during both menstrual cycles. Paired t-test analysis revealed statistically significant pain score reductions from baseline to mid-time and from baseline to eighth hour across all groups ($p <$ 0.001). The heat patch group exhibited the most substantial pain reduction, followed by the analgesic group, with the control group showing modest natural pain resolution patterns.

**Table 2:** Paired t-test showing VAS score of Analgesic, control and heat patch groups at baseline, mid-time, and eight days during both first and second menstrual period

| Group | Time Point Comparison | VAS score in the first menstrual cycle | | | VAS score in the second menstrual cycle | | |
|---|---|---|---|---|---|---|---|
| | | Mean ± SD | Change in Mean | p-value | Mean ± SD | Change in Mean | p-value |
| Heat Patch | Baseline | 7.34 ± 1.61 | - | < 0.0001** | 6.90 ± 1.27 | - | < 0.0001** |
| | Mid-time | 3.58 ± 1.30 | -3.76 | | 3.24 ± 1.27 | -3.66 | |
| | Eighth day | 0.60 ± 0.86 | -6.74 | | 0.50 ± 0.74 | -6.40 | |
| Analgesic | Baseline | 6.06 ± 1.54 | - | < 0.0001** | 5.35 ± 1.97 | - | < 0.0001** |
| | Mid-time | 4.06 ± 1.55 | -2.00 | | 3.67 ± 1.74 | -1.68 | |
| | Eighth day | 2.18 ± 1.52 | -3.88 | | 1.84 ± 1.69 | -3.51 | |
| Control | Baseline | 3.23 ± 2.14 | - | < 0.0001** | 3.43 ± 1.72 | - | < 0.0001** |
| | Mid-time | 2.48 ± 1.94 | -0.75 | | 2.80 ± 1.68 | -0.63 | |
| | Eighth day | 1.70 ± 1.59 | -1.53 | | 1.72 ± 1.55 | -1.71 | |

VAS = Visual Analogue Scale; SD = standard deviation. A paired t-test was performed for within-group temporal comparisons with a significance level set at $p < 0.01$**.

Table 3 presents the comparative analysis of pain score reduction magnitude across treatment groups. One-way ANOVA revealed statistically significant differences in pain reduction between groups during both the first ($F=726.42$, $p < 0.001$) and second menstrual cycles ($F=298.15$, $p < 0.001$). The heat patch group demonstrated superior pain reduction (6.74 and 6.40) compared to the analgesic group (3.88 and 3.51) and control group (1.53 and 0.88) across both cycles.

**Table 3:** Between-group comparison of the magnitude of pain-score reduction from baseline to the eighth hour, first and second menstrual periods

| Difference in VAS score (baseline to 8th hour) | | n = 161 | Mean of difference in VAS score | Std. Deviation | F-statistic | p-value |
|---|---|---|---|---|---|---|
| First menstrual period | Analgesic | 51 | 3.8824 | 0.79113 | 726.42 | < 0.0001** |
| | Control | 60 | 1.5333 | 1.34626 | | |
| | Heat Patch | 50 | 6.7400 | 1.97753 | | |
| Second menstrual period | Analgesic | 51 | 3.5098 | 1.91178 | 298.15 | < 0.0001** |
| | Control | 60 | 0.8833 | 6.55897 | | |
| | Heat Patch | 50 | 6.4000 | 1.41421 | | |

SD = standard deviation. Statistical analysis was performed using one-way ANOVA with post-hoc Bonferroni correction for multiple comparisons, and the F-statistic was derived from the one-way ANOVA test. **p<0.01.

Table 4 presents the temporal pain evolution analysis for the control group using repeated measures ANOVA. Greenhouse-Geisser correction revealed statistically significant differences in mean VAS scores across time points for both first ($F=47.96$, $p < 0.001$) and second menstrual cycles ($F=52.34$, $p < 0.001$). Post-hoc analysis using Bonferroni adjustment demonstrated significant pain score reductions at all time points compared to baseline.

**Table 4:** Comparison of VAS score of the control group in first and second menstrual cycle by repeated measures ANOVA test

| VAS score | At first menstrual cycle | | | At Second menstrual cycle | | |
|---|---|---|---|---|---|---|
| | T1 (Baseline) | T2 (4 hours) | T3 (8 hours) | T1 (Baseline) | T2 (4 hours) | T3 (8 hours) |
| Mean | 3.233 | 2.483 | 1.700 | 3.433 | 2.8 | 1.717 |
| Standard deviation | 2.142 | 1.935 | 1.587 | 1.720 | 1.675 | 1.552 |
| Mean difference from baseline | - | 0.750 | 1.533 | - | 0.633 | 1.716 |
| t-statistic | - | 3.850 | 7.450 | - | 2.910 | 8.550 |
| p-value | - | 0.0001** | 0.0001** | - | 0.001** | 0.0001** |
| 95% Confidence Interval | - | 0.346–1.154 | 1.105–1.962 | - | 0.223–1.043 | 1.222–2.111 |

***A repeated measures ANOVA test was applied: First cycle: F = 47.96, p < 0.001**; Second cycle: F = 52.34 with the significance level set at p < 0.001**. T1 = Time points 1, T2 = Time points 2, T3 = Time points 3, and VAS = Visual Analogue Scale. Greenhouse-Geisser correction and post-hoc analysis using Bonferroni adjustment were applied in the repeated measures ANOVA.***

Table 5 shows the comparison of VAS score of the Analgesic group in first and second menstrual cycle by repeated measures ANOVA test. Repeated measures ANOVA with Greenhouse-Geisser correction revealed statistically significant differences in mean VAS scores across time points for the analgesic group in both first ($F = 681.34$, $p < 0.001$) and second menstrual cycles ($F = 125.003$, $p < 0.001$). Post hoc analysis using Bonferroni adjustment demonstrated significant decreases in VAS scores at all time points compared to baseline, with maximum pain reductions of 3.88 and 3.51 in the first and second menstrual cycles, respectively.

**Table 5:** Comparison of VAS score of the Analgesic group in first and second menstrual cycle by repeated measures ANOVA test

| VAS score | At first menstrual cycle | | | At Second menstrual cycle | | |
|---|---|---|---|---|---|---|
| | T1 (Baseline) | T2 (4 hours) | T3 (8 hours) | T1 (Baseline) | T2 (4 hours) | T3 (8 hours) |
| Mean | 6.059 | 4.059 | 2.176 | 5.353 | 3.667 | 1.843 |
| Standard deviation | 1.541 | 1.554 | 1.519 | 1.968 | 1.739 | 1.689 |
| Mean difference from baseline | - | 2.000 | 3.883 | - | 1.686 | 3.51 |
| t-statistic | - | 8.92 | 17.65 | - | 6.89 | 14.81 |
| p-value | - | 0.0001** | 0.0001** | - | 0.0001** | 0.0001** |
| 95% Confidence Interval | - | 1.740 – 2.260 | 3.608 – 4.157 | - | 1.184 – 2.189 | 2.847 – 4.173 |

***A repeated measures ANOVA test was applied: First cycle: F = 681.34, p < 0.001**; Second cycle: F = 125.003 with the significance set at p < 0.001**. T1 = Time points 1; T2 = Time points 2; T3 = Time points 3; VAS = Visual Analogue Scale, Greenhouse-Geisser correction and post-hoc analysis using Bonferroni adjustment were applied in repeated measures ANOVA.***

Table 6 shows the comparison of VAS score of the Heat Patch group in first and second menstrual cycle by repeated measures ANOVA test. Repeated measures ANOVA with Greenhouse-Geisser correction revealed statistically significant differences in mean VAS scores across time points for the heat patch group in both first ($F = 474.08$, $p < 0.001$) and second menstrual cycles ($F = 712.11$, $p < 0.001$). Post hoc analysis using Bonferroni adjustment demonstrated significant decreases in VAS scores at all time points compared to baseline, with maximum pain reductions of 6.74 and 6.40 in the first and second menstrual cycles, respectively.

**Table 6:** Comparison of VAS score of the Heat Patch group in first and second menstrual cycle by repeated measures ANOVA test

| VAS score | At first menstrual cycle | | | At second menstrual cycle | | |
|---|---|---|---|---|---|---|
| | T1 (Baseline) | T2 (4 hours) | T3 (8 hours) | T1 (Baseline) | T2 (4 hours) | T3 (8 hours) |
| Mean | 7.34 | 3.58 | 0.6 | 6.9 | 3.24 | 0.5 |
| Standard deviation | 1.611 | 1.295 | 0.857 | 1.265 | 1.27 | 0.735 |
| Mean difference from baseline | - | 3.76 | 6.74 | - | 3.66 | 6.4 |
| t-statistic | - | 12.45 | 24.67 | - | 14.82 | 28.91 |
| p-value | - | 0.0001** | 0.0001** | - | 0.0001** | 0.0001** |
| 95% Confidence Interval | - | 3.356–4.164 | 6.047–7.433 | - | 3.302–4.018 | 5.904–6.896 |

A repeated measures ANOVA test was applied: First cycle: $F = 474.08$, $p < 0.001$**; Second cycle: $F = 712.11$, with the significance set at $p < 0.001$**. T1 = Time points 1; T2 = Time points 2; T3 = Time points 3; VAS = Visual Analogue Scale. Greenhouse-Geisser correction and post-hoc analysis using Bonferroni adjustment were applied in repeated measures ANOVA.

## DISCUSSION

This investigation demonstrates superior therapeutic efficacy of local heat patch application versus conventional oral analgesics in primary dysmenorrhea management. Heat patch intervention achieved mean VAS score reductions of 6.74 and 6.40 across consecutive menstrual cycles, representing 92% pain reduction compared to 64% with analgesics, establishing clinically meaningful therapeutic benefits.

The present study's baseline pain characteristics align closely with established epidemiological data from comparable populations. Aktas reported that 56.5% of students utilized heat application and 69% employed analgesics for pain management, with mean pain severity of 5.78 ± 2.45 on the VAS scale, demonstrating consistency with our baseline measurements.[14] However, the structured heat patch protocol implemented here achieved considerably greater pain reduction (mean difference: 6.74 in the first cycle) than oral analgesics (mean difference: 3.88), substantially surpassing the general comfort-level improvements reported in Aktaş's study, which found both interventions only moderately effective.[14]

The present investigation shares important methodological similarities with Potur and Komorucu's research conducted in Istanbul, which employed a comparable three-arm design comparing heat patch application, analgesics, and control groups.[11] However, significant disparities emerged in outcome measurements, as their study reported no statistically significant differences between intervention groups at 4 and 8-hour assessment intervals during both menstrual cycles ($P > 0.05$). Conversely, the present study demonstrated marked differences in pain reduction across all groups, with the heat patch group achieving significantly greater pain reduction (mean difference: 6.74 in first cycle) compared to both analgesic (3.88) and control groups (1.53) ($p < 0.001$). This disparity in findings may be attributed to several methodological factors, including extended observation periods within each menstrual cycle, standardized heat patch application protocols, and potentially varying baseline pain characteristics specific to the rural South Indian population demographic.

The findings demonstrate remarkable consistency with Akin et al.'s large-scale randomized, active-controlled study involving 367 subjects, which compared heat therapy efficacy to oral acetaminophen.[15] Their investigation established that heat therapy was significantly superior to acetaminophen for pain relief over an 8-hour observation period (means of 2.48 versus 2.17, $p = 0.015$), particularly during hours 3-6 post-intervention. Similarly, the present study documented superior pain reduction with heat patch application (mean difference: 6.74) compared to analgesics (3.88) across both consecutive menstrual cycles. Akin et al.'s documentation of reduced muscle tightness and cramping with heat therapy (means of 40.4 versus 44.5, $p = 0.04$) provides mechanistic support for the present study's clinical observation.[15] Additionally, their findings regarding decreased fatigue and reduced mood disturbances with heat therapy suggest broader quality-of-life benefits extending beyond pure analgesic effects.

Further validation emerges from another Akin et al. investigation demonstrating significantly greater pain relief with heated patch plus placebo (mean 3.27, $P < 0.001$) compared to unheated patch plus placebo (mean 1.95), paralleling the present study's findings of superior pain reduction with active heat therapy.[13] The present investigation extends these findings by demonstrating sustained efficacy of heat therapy as monotherapy across two consecutive menstrual cycles, with mean VAS score reductions of 6.74 and 6.40 in the first and second cycles respectively.

Contrasting results emerged from Rigi et al.'s comparative analysis of heat patch application versus ibuprofen utilizing the shortened McGill Pain Questionnaire (SF-MPQ), which found no statistically significant differences between interventions.[16] These divergent findings contrast markedly with the present study's results, where heat patch

application demonstrated significantly superior pain reduction (mean difference: 6.74 in first cycle) compared to analgesics (mean difference: 3.88). This discordance may be attributed to methodological variations, pain assessment instrument differences, or population-specific characteristics. The present study's comprehensive observation protocol across two consecutive menstrual cycles may have provided more comprehensive efficacy assessment compared to Rigi et al.'s single-cycle evaluation methodology.[16]

Lee et al. conducted a multicenter randomized double-blind placebo-controlled trial investigating far-infrared-emitting sericite belts for dysmenorrhea management, demonstrating gradual pain severity reduction across three treatment cycles with baseline VAS scores (7.27±0.19 experimental; 7.38±0.19 control) comparable to the present study's baseline measurements.[17] While their experimental group showed sustained pain reduction during extended follow-up periods, the magnitude of improvement was less pronounced than observed in the present study's heat patch group (mean difference: 6.74 in first cycle). This efficacy differential may be attributed to distinct heat delivery mechanisms—direct thermal application via adhesive patches in the present study versus far-infrared radiation in Lee et al.'s investigation.[17]

The present findings contrast with Ouda et al.'s quasi-experimental study comparing heat application and exercise interventions among nursing students.[18] While their investigation demonstrated effectiveness of both heat application and stretching exercises in dysmenorrhea management, they concluded that stretching and core strengthening exercises were superior to heat application alone. This differs from the present results, where heat patch application demonstrated remarkable analgesic efficacy. The divergence in findings may be attributed to heat application methodology differences, study population variations, and cultural contextual factors between rural South India and their university setting. Similarly, Elmoniem et al. reported that stretching exercises were more effective than heat application in reducing dysmenorrhea severity, frequency, and duration.[19] These contrasting findings may be attributed to heat application methodology differences, demographic variations between university and rural populations, and varying cultural contexts between Egypt and rural South India.

The present study findings receive substantial support from a robust evidence base demonstrating heat-based intervention efficacy for primary dysmenorrhea. Widianti et al. reported statistically significant pain score reductions with warm bandage application ($p<0.05$), emphasizing cost-effectiveness and minimal adverse effects.[20] Thabet et al. demonstrated that heat compresses were more effective than alternative non-pharmacological interventions such as knee-chest positioning among adolescent females with moderate to severe primary dysmenorrhea.[21] The systematic review by Lee and Jo provided additional validation, analyzing six studies that consistently demonstrated heat therapy's superiority over both placebo and analgesic medications in managing menstrual pain.[22] This evidence base received further strengthening from Armour et al.'s meta-analysis, which highlighted heat intervention as an effective self-care technique for dysmenorrhea management.[23]

Heat therapy for primary dysmenorrhea has demonstrated promising therapeutic results, though outcomes exhibit variability across different investigational studies. In the present research, significant pain reduction was observed, with mean VAS score reductions of 6.74 and 6.40. However, several factors may explain outcome variations reported in contemporary literature.[13–15] Primarily, heat application methodology varies substantially between studies, including thermal belts, hot water bottles, electric heating pads, and adhesive heat patches. These methodological variations differ in temperature consistency maintenance, application duration capabilities, and thermal penetration depth, all factors that significantly influence therapeutic efficacy. Additionally, baseline pain severity among study participants substantially influences treatment response outcomes, while environmental and cultural factors contribute to outcome variability. Methodological differences in pain assessment tools and measurement timing contribute to result heterogeneity, and variations in control group definitions affect comparative outcome measurements.

**Strength of the study**

The use of the Visual Analog Scale (VAS) for pain assessment provides a standardized and quantitative method for measuring pain intensity. Statistical rigor was maintained through multiple advanced statistical techniques, including one-way ANOVA, paired t-test, and repeated measures ANOVA with Greenhouse- Geisser correction, ensuring comprehensive and reliable data analysis. The inclusion of demographic equivalence testing across groups (age, BMI, age at menarche) minimizes potential confounding variables and enhances the study's internal validity.

**Limitation**

The research was conducted exclusively among medical students in a rural South Indian population, which significantly restricts generalizability to broader demographic groups. The sample size of approximately 50-60 participants per group is relatively modest, potentially limiting statistical power and comprehensive representation. Additionally, the study did not extensively explore potential physiological mechanisms underlying heat patch effectiveness or compare different types of heat patches. The lack of detailed patient-reported outcomes beyond pain scores and absence of long-term follow-up further constrains the comprehensive understanding of intervention efficacy.

## CONCLUSION

This prospective comparative study demonstrates significant clinical evidence supporting local heat patch application as an effective and non-pharmacological

intervention for primary dysmenorrhea management. To optimize dysmenorrhea care, healthcare providers should prioritize comprehensive education on self-management strategies, including the use of heat therapy, alongside pharmacological options. Additionally, further research exploring the long-term effects and comparative efficacy of heat therapy with other interventions can provide valuable insights into personalized dysmenorrhea management strategies. Overall, our study contributes to enhancing understanding and promoting evidence-based interventions for young females suffering from dysmenorrhea.

**Conflicts of interest**

The authors declare no conflicts of interest.

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**Author contributions**

Conceptualization and study design: T.M.; Data collection: S.V.; Formal analysis and interpretation: T.M., N.G.; Drafting of the manuscript: S.V., T.M.; Critical revision for important intellectual content: N.G., K.K.; Supervision: T.M., K.K. All authors reviewed and approved the final manuscript. Only individuals meeting authorship criteria are listed as authors.

**AI use statement**

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**REFERENCES**

1. Karout S, Soubra L, Rahme D, Karout L, Khojah HMJ, Itani R. Prevalence, risk factors, and management practices of primary dysmenorrhea among young females. BMC Womens Health. 2021 Nov 8;21:392. doi:10.1186/s12905-021-01532-w PubMed PMID: 34749716; PubMed Central PMCID: PMC8576974.
2. Durain D. Primary Dysmenorrhea: Assessment and Management Update. J Midwife Womens Health. 2004 Nov 12;49(6):520–8. doi:10.1016/j.jmwh.2004.08.013
3. O'Connell K, Davis AR, Westhoff C. Self-treatment Patterns among Adolescent Girls with Dysmenorrhea. J Pediatr Adolesc Gynecol. 2006 Aug;19(4):285–9. doi:10.1016/j.jpag.2006.05.004
4. Lin JA, Wong CS, Lee MS, Ko SC, Chan SM, Chen JJY, et al. Successful Treatment of Primary Dysmenorrhea by Collateral Meridian Acupressure Therapy. J Manip Physiol Ther. 2010 Jan;33(1):70–5. doi:10.1016/j.jmpt.2009.11.003
5. Eryilmaz G, Ozdemir F. Evaluation of Menstrual Pain Management Approaches by Northeastern Anatolian Adolescents. Pain Manag Nurs. 2009 Mar;10(1):40–7. doi:10.1016/j.pmn.2008.09.001
6. Banikarim C, Chacko MR, Kelder SH. Prevalence and Impact of Dysmenorrhea on Hispanic Female Adolescents. Arch Pediatr Adolesc Med. 2000 Dec 1;154(12):1226. doi:10.1001/archpedi.154.12.1226
7. Holtzman DA, Petrocco-Napuli KL, Burke JR. Prospective Case Series on the Effects of Lumbosacral Manipulation on Dysmenorrhea. J Manip Physiol Ther. 2008 Mar;31(3):237–46. doi:10.1016/j.jmpt.2008.02.005
8. Apay SE, Arslan S, Akpinar RB, Celebioglu A. Effect of Aromatherapy Massage on Dysmenorrhea in Turkish Students. Pain Manag Nurs. 2012 Dec;13(4):236–40. doi:10.1016/j.pmn.2010.04.002
9. Jun EM, Chang S, Kang DH, Kim S. Effects of acupressure on dysmenorrhea and skin temperature changes in college students: A non-randomized controlled trial. Int J Nurs Stud. 2007 Aug;44(6):973–81. doi:10.1016/j.ijnurstu.2006.03.021
10. Rakhshaee Z. Effect of Three Yoga Poses (Cobra, Cat and Fish Poses) in Women with Primary Dysmenorrhea: A Randomized Clinical Trial. J Pediatr Adolesc Gynecol. 2011 Aug;24(4):192–6. doi:10.1016/j.jpag.2011.01.059
11. Potur DC, Kömürcü N. The Effects of Local Low-Dose Heat Application on Dysmenorrhea. J Pediatr Adolesc Gynecol. 2014 Aug;27(4):216–21. doi:10.1016/j.jpag.2013.11.003
12. Delgado DA, Lambert BS, Boutris N, McCulloch PC, Robbins AB, Moreno MR, et al. Validation of Digital Visual Analog Scale Pain Scoring With a Traditional Paper-based Visual Analog Scale in Adults. J Am Acad Orthop Surg Glob Res Rev. 2018 Mar 23;2(3):e088. doi:10.5435/JAAOSGlobal-D-17-00088 PubMed PMID: 30211382; PubMed Central PMCID: PMC6132313.
13. Akin MD, Weingand KW, Hengehold DA, Goodale MB, Hinkle RT, Smith RP. Continuous Low-Level Topical Heat in the Treatment of Dysmenorrhea. Obstet Gynecol. 2001;97(3):343–9. doi:10.1016/s0029-7844(00)01163-7
14. Aktaş D. Prevalence and Factors Affecting Dysmenorrhea in Female University Students: Effect on General Comfort Level. Pain Manag Nurs. 2015 Aug;16(4):534–43. doi:10.1016/j.pmn.2014.10.004 PubMed PMID: 26256218.

15. Akin M, Price W, Rodriguez G, Erasala G, Hurley G, Smith RP. Continuous, low-level, topical heat wrap therapy as compared to acetaminophen for primary dysmenorrhea. J Reprod Med. 2004 Sep;49(9):739–45. PubMed PMID: 15493566.

16. Navvabi Rigi S, Kermansaravi F, Navidian A, Safabakhsh L, Safarzadeh A, Khazaian S, et al. Comparing the analgesic effect of heat patch containing iron chip and ibuprofen for primary dysmenorrhea: a randomized controlled trial. BMC Womens Health. 2012 Aug 22;12:25. doi:10.1186/1472-6874-12-25 PubMed PMID: 22913409; PubMed Central PMCID: PMC3492023.

17. Lee CH, Roh JW, Lim CY, Hong JH, Lee JK, Min EG. A multicenter, randomized, double-blind, placebo-controlled trial evaluating the efficacy and safety of a far infrared-emitting sericite belt in patients with primary dysmenorrhea. Complement Ther Med. 2011 Aug;19(4):187–93. doi:10.1016/j.ctim.2011.06.004 PubMed PMID: 21827932.

18. Ouda K, Latif S, Nabil T. A study of the effect of heat application on relieving dysmenorrheal pain among young females. Afr J Nurs Midwifery. 2017 Jun;5(6):727–35.

19. Elmoniem SOA, Abd-Elhakam EM, Abd El Aliem RS. Effect of Heat Application versus Stretching Exercises on Relieving Discomforts of Primary Dysmenorrhea among University Student Girls. IOSR Journal of Nursing and Health Science. 2020;49(4):20–32. doi:10.9790/1959-0904042032

20. Widianti W, Nurazizah YS, Nurkania V, Fauzi A, Hidayat A, Herdiawan Y, et al. The Effect of Warm Compress on Lowering Dysmenorrhea Pain. General Nursing Science. 2021 Dec 30;2(2):54–60. doi:10.56359/gj.v2i2.22

21. Thabet HA, Fahmy Elsaba HAH, Abd Elsattar Hassan AH. Effects of Two Non-pharmacological Pain Relief Interventions on the Severity of Pain among Adolescent Girls Complaining from Primary Dysmenorrhea. Int j novel res healthc nurs. 2020;7(3):247–61.

22. Jo J, Lee SH. Heat therapy for primary dysmenorrhea: A systematic review and meta-analysis of its effects on pain relief and quality of life. Sci Rep. 2018 Nov 2;8:16252. doi:10.1038/s41598-018-34303-z PubMed PMID: 30389956; PubMed Central PMCID: PMC6214933.

23. Armour M, Smith CA, Steel KA, Macmillan F. The effectiveness of self-care and lifestyle interventions in primary dysmenorrhea: a systematic review and meta-analysis. BMC Complement Altern Med. 2019 Dec;19(1):22. doi:10.1186/s12906-019-2433-8