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EFFECTIVENESS OF HOAT HUYET NHAT NHAT IN REDUCING PAIN AND IMPROVING QUALITY OF LIFE IN PATIENTS WITH PRIMARY DYSMENORRHEA

Vu Thi Thuy Linh[1*], Le Thanh Xuan[2], Le Thi Minh Phuong[2], Vu Ha My[3]

[1]*Dai Nam University - 1 Xom Street, Phu Luong Ward, Hanoi City, Vietnam*
[2]*Hanoi Medical University - 1 Ton That Tung, Kim Lien Ward, Hanoi City, Vietnam*
[3]*University of Medicine and Pharmacy, Vietnam National University, Hanoi - 144 Xuan Thuy, Cau Giay Ward, Hanoi City, Vietnam*

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ABSTRACT

Objective: To evaluate the effectiveness of Hoat Huyet Nhat Nhat in reducing pain and improving quality of life in patients with primary dysmenorrhea.

Methods: A randomized, double-Blind, placebo - controlled trial on 100 patients diagnosed with primary dysmenorrhea. Participants were randomly assigned to two groups: 50 received Hoat Huyet Nhat Nhat and 50 received placebo, for three consecutive menstrual cycles. Outcomes were assessed using the Visual Analog Scale (VAS) for pain intensity, duration of pain, rescue Naproxen consumption, and quality of life measured by EQ-5D-5L.

Results: In the Hoat Huyet Nhat Nhat group, mean VAS score decreased from 6.72 ± 1.14 to 4.14 ± 2.08 ($p < 0.01$), mean pain duration reduced from 18.9 ± 6.88 to 10.82 ± 7.86 hours ($p < 0.01$), and mean Naproxen consumption was significantly lower (4.0 ± 2.1 mg vs. 9.5 ± 3.4 mg in the placebo group, $p < 0.01$). Quality of life improved significantly with EQ-5D-5L increasing from 0.52 ± 0.18 to 0.80 ± 0.18 ($p < 0.01$), while the placebo group showed no significant changes. Conclusion: Hoat Huyet Nhat Nhat is effective in reducing menstrual pain, shortening pain duration, lowering the need for rescue analgesics, and improving quality of life in patients with primary dysmenorrhea. It is a safe and feasible therapeutic option for clinical practice.

Keywords: Hoat Huyet Nhat Nhat, primary dysmenorrhea, Visual Analog Scale, EQ-5D-5L, quality of life.

1. INTRODUCTION

Primary dysmenorrhea is one of the most common gynecological disorders among women of reproductive age. It is characterized by cramping pain in the lower abdomen, which may radiate to the back or thighs, and is often accompanied by symptoms such as nausea, diarrhea, dizziness, and fatigue [1]. Its prevalence has been reported to be as high as nearly 90%, with the highest rate observed among adolescents [2]. Although primary dysmenorrhea is not a life-threatening condition, it substantially impairs quality of life as well as work and academic performance [2]. Therefore, primary dysmenorrhea is not only an individual health problem but also a medical and social burden that warrants greater attention.

Current treatment approaches are mainly based on nonsteroidal anti-inflammatory drugs (NSAIDs) and oral contraceptives [1], [3]. Although these medications can provide rapid pain relief, their effects are often short-term, with a high likelihood of recurrence and potential drug resistance, and they may be associated with several adverse effects, including headache, nausea, and peptic ulceration. These limitations highlight the need to identify alternative therapeutic approaches that are safer, more effective, and more sustainable.

According to traditional medicine, dysmenorrhea falls under the category of "tong jing" and is primarily attributed to qi stagnation, blood stasis, or deficiency-cold, which results in impaired circulation of qi and blood [4]. Traditional medicine therapies, particularly herbal preparations, have been shown to relieve pain, regulate menstruation, and improve overall health. Hoat Huyet Nhat Nhat is a multi-herbal preparation with blood-tonifying, blood-activating, and qi-regulating effects, indicated for conditions associated with blood deficiency and blood stasis. However, clinical evidence regarding its use in the treatment of dysmenorrhea remains limited, and few controlled comparative studies have been conducted to confirm its therapeutic value.

To provide further scientific evidence for the clinical application of Hoat Huyet Nhat Nhat in the treatment of dysmenorrhea, this study was conducted to evaluate its effects on menstrual pain reduction and quality-of-life improvement in patients with primary dysmenorrhea.

2. SUBJECTS AND METHODS

2.1. Study design

This was a randomized, double-blind, placebo-controlled clinical trial.

2.2. Study period and setting

Study period: From July 2021 to July 2022.

Study setting: Department of Traditional Medicine, Hanoi Medical University Hospital.

2.3. Study participants

The study participants were female patients with primary dysmenorrhea who attended outpatient examination and treatment at the Department of Traditional Medicine, Hanoi Medical University Hospital.

*Corresponding author
Email: thuylinhyct1111@gmail.com **Phone:** (+84) 868685045 **Https:**//doi.org/10.52163/yhc.v67iE1.5280

- Inclusion criteria:

+ Female patients aged 18–35 years.

+ Diagnosis of primary dysmenorrhea, with gynecological examination and ultrasound performed to exclude organic causes [5].

+ Regular menstrual cycles, ranging from 21 to 35 days.

+ VAS score ≥ 4 in at least one-third of recent menstrual cycles.

+ Voluntary agreement to participate in the study and provision of written informed consent.

- Exclusion criteria:

+ Sexually transmitted infections within the previous three months.

+ Secondary dysmenorrhea, including endometriosis, uterine fibroids, pelvic inflammatory disease, or cervical stenosis.

+ History or current presence of peptic ulcer disease, or contraindications to NSAIDs, including hepatic or renal impairment, asthma, coagulation disorders, or severe cardiovascular disease.

+ Medical emergency conditions.

+ Allergy to any component of Hoat Huyet Nhat Nhat or naproxen.

+ Current or recent use of other medications for dysmenorrhea or oral contraceptives during or immediately before the study.

2.4. Sample size and sampling method

Sample size: The study included 100 patients who met the eligibility criteria specified in Section 2.1 during the study period.

Sampling method: A total of 100 eligible patients were interviewed, clinically examined, and underwent laboratory testing using a standardized case report form. They were then randomly allocated by envelope-coded randomization into two treatment groups at a 1:1 ratio.

- Hoat Huyet Nhat Nhat group (n = 50): Patients took two tablets per dose, twice daily. The first dose was initiated five days before the expected onset of menstruation and continued for a maximum of 10 days or until the end of menstruation.

- Placebo group (n = 50): Patients took two placebo tablets per dose, twice daily. The first dose was initiated five days before the expected onset of menstruation and continued for a maximum of 10 days or until the end of menstruation.

2.5. Study variables, indicators, and research procedure

2.5.1. Study indicators

- General patient characteristics, including age, menstrual cycle, number of menstrual days, and traditional medicine syndrome pattern.

- Treatment outcomes, including VAS score, duration of pain, number of rescue naproxen tablets used, quality of life assessed by the EQ-5D-5L, and adverse events.

2.5.2. Outcome assessment

- Pre–post comparisons and between-group comparisons of VAS score, duration of pain, naproxen use, and EQ-5D-5L score.

- Subgroup analysis according to traditional medicine syndrome pattern.

- Treatment effectiveness was determined based on statistically significant improvement, defined as $p < 0.05$.

2.6. Data collection methods

Study indicators, including VAS score, duration of pain, number of naproxen tablets used, and EQ-5D-5L score, were recorded from medical records, home monitoring forms, and direct interviews during each menstrual cycle.

Research procedure:

- Eligible female patients aged 18–35 years who attended the Department of Traditional Medicine, Hanoi Medical University Hospital were selected and provided written informed consent to participate in the study.

- A pre-treatment clinical examination was conducted during the most recent menstrual cycle. This included measurement of vital signs, assessment of pain intensity, and classification of traditional medicine syndrome patterns, including qi stagnation and blood stasis, cold congealing with blood stasis, blood deficiency, damp-heat pouring downward, and liver-kidney deficiency [4].

- Pre-treatment paraclinical investigations included complete blood count, blood biochemistry tests — creatinine, AST, and ALT — and abdominal ultrasound.

- Participants were randomly allocated into groups, provided with the study medication and naproxen, and instructed on how to complete the home monitoring form, including VAS score, number of pain hours, number of analgesic tablets used, and any abnormal symptoms. They were also instructed on naproxen use: Naproxen was to be used only when dysmenorrhea exceeded the patient's tolerability threshold, defined as a VAS score of 6 or higher. The recommended dosage was one tablet per dose, twice daily, with an interval of at least 6 hours between doses, for a maximum duration of 5 days.

Outcome assessment:

The outcomes were recorded in the medical records, and medication adherence was monitored.

Follow-up indicators: VAS score, duration of pain, and number of naproxen tablets used were recorded at all pain episodes using home monitoring forms and interviews.

Quality of life, assessed using the EQ-5D-5L, and paraclinical parameters were evaluated at baseline and after completion of the menstrual cycle during which the study medication was used.

2.7. Data analysis

Data were collected and analyzed using biomedical statistical methods with SPSS version 20.0.

2.8. Research ethics

The study was conducted in accordance with ethical principles for biomedical research. The research protocol was approved by the Master's Thesis Proposal Review Committee of Hanoi Medical University and received permission from Hanoi Medical University Hospital.

3. RESULTS

3.1. Characteristics of the study participants

The mean age at menarche in both groups was approximately 13.3 years, with most participants reporting menarche between 13 and 16 years of age. There was no significant difference between the study group (13.38 ± 1.39 years) and the control group (13.32 ± 1.13 years) ($p > 0.05$). The mean menstrual cycle length was 30.98 ± 2.44 days, ranging from 27 to 35 days, with no significant difference between the two groups ($p > 0.05$). The duration of menstruation during the three most recent menstrual cycles was predominantly 4–6 days. The mean durations in the study group were 5.32 ± 0.96,

5.40 ± 0.94, and 5.38 ± 1.01 days, respectively, compared with 5.02 ± 1.04, 5.18 ± 1.06, and 5.18 ± 1.16 days, respectively, in the control group. These differences were not statistically significant (p > 0.05).

Regarding traditional medicine syndrome patterns, qi stagnation and blood stasis was the most common pattern, accounting for 74% of all participants: 35/50 patients (70%) in the study group and 39/50 patients (78%) in the control group. Deficiency-cold was less frequent, observed in 26% of the study group (13/50) and 14% of the control group (7/50). Blood deficiency was the least common pattern, accounting for 4% of the study group (2/50) and 8% of the control group (4/50). The distribution of syndrome patterns did not differ significantly between the two groups (p > 0.05).

3.2. Analgesic Effects of Hoat Huyet Nhat Nhat on Dysmenorrhea

Effect on the Mean VAS Pain Score

Between-group p-value before treatment > 0.05; after treatment < 0.01

Comment Figure 1: Before the intervention, the mean VAS scores were comparable between the two groups (p > 0.05). After treatment, the VAS score in the Hoat Huyet Nhat Nhat group decreased to 4.14 ± 2.07, compared with 5.20 ± 1.84 in the placebo group, with a statistically significant difference (p < 0.01). The improvement in VAS score was greater in the Hoat Huyet Nhat Nhat group (–2.58 ± 1.71) than in the placebo group (–1.64 ± 2.30), demonstrating a marked analgesic effect.

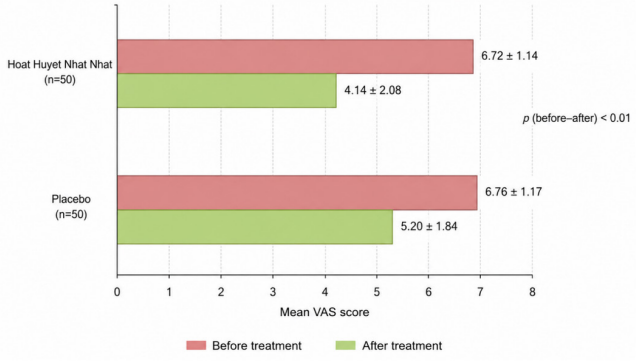


Figure 1. Changes in mean VAS scores before and after the intervention

Effect on the improvement in mean VAS score according to traditional medicine syndrome pattern

Table 1. Improvement in mean VAS score according to traditional medicine pattern

TM pattern	Time point	Hoat Huyet Nhat Nhat (n = 50) VAS ($\bar{X}$ ± SD)	Placebo (n = 50) VAS ($\bar{X}$ ± SD)	p between groups
Qi stagnation and blood stasis	Before treatment	6.71 ± 1.22	6.82 ± 1.19	> 0.05
	After treatment	3.86 ± 1.85	5.41 ± 1.87	< 0.05
	p before-after	< 0.001	< 0.05	
Blood deficiency	Before treatment	7.00 ± 1.41	6.75 ± 0.95	> 0.05
	After treatment	5.50 ± 3.53	5.25 ± 2.217	> 0.05
	p before-after	< 0.01	< 0.01	
Deficiency-cold	Before treatment	6.69 ± 0.95	6.43 ± 1.27	> 0.05
	After treatment	4.69 ± 2.46	6.57 ± 1,71	< 0.01
	p before-after	< 0.05	> 0.05	

Comment: In the qi stagnation and blood stasis pattern, the Hoat Huyet Nhat Nhat group showed a more pronounced reduction in VAS score than the placebo group (3.86 ± 1.85 vs 5.41 ± 1.87; p < 0.05). In the blood deficiency pattern, both groups showed a significant reduction in VAS score (p < 0.01), with comparable levels of improvement. In the deficiency-cold pattern, only the Hoat Huyet Nhat Nhat group demonstrated a significant reduction in VAS score (p < 0.05), whereas no significant change was observed in the placebo group (p > 0.05).

Effect on the duration of dysmenorrhea

Table 2. Comparison of dysmenorrhea duration and analgesic use between the two groups

Characteristic	Time point	Hoat Huyet Nhat Nhat (n = 50)	Placebo (n = 50)	p between groups
Number of dysmenorrhea days ($\bar{X}$ ± SD)	Before treatment	1.62 ± 0.64	1.68 ± 0.51	> 0.05
	After treatment	1.24 ± 0.69	1.46 ± 0.54	> 0.05
	p before-after	< 0.001	< 0.01	
Number of dysmenorrhea hours ($\bar{X}$ ± SD)	Before treatment	18.9 ± 6.88	18.68 ± 5.83	> 0.05
	After treatment	10.82 ± 7.86	14.24 ± 7.09	< 0.01
	p before-after	< 0.001	< 0.01	
Rescue naproxen use ($\bar{X}$ ± SD)	During study	4.0 ± 2.1	9.5 ± 3.4	< 0.01

Comment: Before the intervention, the number of days and hours of dysmenorrhea were comparable between the two groups (p > 0.05). After treatment, both groups showed reductions in the number of days and hours of pain (p < 0.01), with a greater reduction observed in the Hoat Huyet Nhat Nhat group, particularly in the duration of pain in hours (10.82 ± 7.86 vs. 14.24 ± 7.09; p < 0.01). Naproxen use was markedly lower in the Hoat Huyet Nhat Nhat group than in the placebo group (4.0 ± 2.1 vs. 9.5 ± 3.4; p < 0.01).

3.3. Effects on Quality-of-Life Improvement

Mean quality-of-life score before and after treatment

Comment Table 3: Before the intervention, the quality-of-life index was comparable between the two groups (p > 0.05). After treatment, both groups showed significant improvement (p < 0.01), with a greater increase observed in the Hoat Huyet Nhat Nhat group (0.27 ± 0.20 vs. 0.16 ± 0.20; p < 0.01).

Table 3. EQ-5D-5L quality-of-life index before and after treatment

EQ-5D-5L index ($\bar{X}$ ± SD)	Hoat Huyet Nhat Nhat (n = 50)	Placebo (n = 50)	p between groups
Before treatment	0.52 ± 0.18	0.51 ± 0.17	> 0.05
After treatment	0.80 ± 0.18	0.68 ± 0.19	< 0.01
p before-after	< 0.001	< 0.01	
Improvement in QoL score	0.27 ± 0.20	0.16 ± 0.20	< 0.01

Effect on quality-of-life improvement according to traditional medicine syndrome pattern

Table 4. Changes in the EQ-5D-5L quality-of-life index according to traditional medicine syndrome pattern

TM pattern	Time point	Hoat Huyet Nhat Nhat (n = 50) EQ-5D-5L ($\bar{X}$ ± SD)	Placebo (n = 50) EQ-5D-5L ($\bar{X}$ ± SD)	p between groups
Qi stagnation and blood stasis	Before treatment	0.47 ± 0.10	0.48 ± 0.13	> 0.05
	After treatment	0.75 ± 0.08	0.60 ± 0.10	< 0.05
	p before-after	< 0.01	< 0.05	
Blood deficiency	Before treatment	0.52 ± 0.18	0.51 ± 0.17	> 0.05
	After treatment	0.83 ± 0.16	0.66 ± 0.19	< 0.01
	p before-after	< 0.001	< 0.05	
Deficiency-cold	Before treatment	0.50 ± 0.18	0.51 ± 0.07	> 0.05
	After treatment	0.81 ± 0.03	0.70 ± 0.14	< 0.05
	p before-after	< 0.001	< 0.01	

Comment: In the qi stagnation and blood stasis pattern, the Hoat Huyet Nhat Nhat group showed a greater improvement in the quality-of-life index than the placebo group (0.75 ± 0.08 vs. 0.60 ± 0.10; p < 0.05). In the blood deficiency pattern, both groups showed significant improvement (p < 0.05); however, the Hoat Huyet Nhat Nhat group achieved a greater increase (0.83 ± 0.16 vs. 0.66 ± 0.19; p < 0.01). In the deficiency-cold pattern, both groups improved significantly (p < 0.05), with a superior effect observed in the Hoat Huyet Nhat Nhat group (0.81 ± 0.03 vs. 0.70 ± 0.14).

4. DISCUSSION

4.1. Analgesic Effects on Dysmenorrhea

The results showed that the mean VAS scores decreased after treatment in both groups; however, the reduction was more pronounced in the Hoat Huyet Nhat Nhat group. Specifically, the VAS score in the study group decreased from 6.72 ± 1.14 to 4.14 ± 2.07, whereas that in the placebo group decreased from 6.76 ± 1.17 to 5.20 ± 1.84. The mean improvement in the Hoat Huyet Nhat Nhat group was –2.58 ± 1.71, which was greater than that in the placebo group (–1.64 ± 2.30), with a statistically significant difference (p < 0.05). This finding is consistent with the study by Nguyen Ton Quyen using traditional medicine formulas, which also demonstrated a significant analgesic effect on the VAS scale [5]. International studies on the therapeutic effects of traditional herbal formulas for primary dysmenorrhea further support this observation [6].

The Hoat Huyet Nhat Nhat group showed a reduction in mean pain duration from 18.9 ± 6.88 hours to 10.82 ± 7.86 hours, whereas the placebo group decreased only to 14.24 ± 7.09 hours. The difference between the two groups was statistically significant (p < 0.01). In addition, naproxen use in the study group was markedly lower than in the placebo group (4.0 ± 2.1 mg vs. 9.5 ± 3.4 mg; p < 0.01). These findings indicate that the medication not only reduced pain intensity but also shortened pain duration and decreased the need for rescue NSAID use, thereby potentially reducing the risk of adverse effects.

This effect may be explained by the composition of Hoat Huyet Nhat Nhat, which includes medicinal herbs such as Ligusticum chuanxiong (Chuanxiong), Paeonia lactiflora/Paeonia veitchii (red peony root), motherwort, and Achyranthes root. These herbs have qi-regulating, blood-activating, and blood-stasis-resolving properties, thereby promoting menstrual blood circulation. Consequently, participants in the study group experienced reductions in menstrual pain and pain duration during each menstrual cycle, leading to a lower requirement for rescue analgesics. However, due to limitations in time and funding, we were unable to conduct longer-term follow-up to confirm whether the analgesic effect of Hoat Huyet Nhat Nhat is sustained in subsequent menstrual cycles after treatment.

Analysis by traditional medicine syndrome pattern showed that, in the Hoat Huyet Nhat Nhat group, all three

patterns demonstrated significant improvement in VAS scores: qi stagnation and blood stasis decreased from 6.71 ± 1.22 to 3.86 ± 1.85; blood deficiency decreased from 7.0 ± 1.41 to 5.50 ± 3.53; and deficiency-cold decreased from 6.69 ± 0.95 to 4.69 ± 2.46. In contrast, in the placebo group, only the qi stagnation and blood stasis and blood deficiency patterns showed slight reductions, while the deficiency-cold pattern remained almost unchanged. These findings suggest that the analgesic effect of Hoat Huyet Nhat Nhat was consistent across multiple traditional medicine syndrome patterns, with particularly notable effectiveness in the qi stagnation and blood stasis and deficiency-cold patterns.

4.2. Effects on Quality-of-Life Improvement

Dysmenorrhea has been shown to substantially affect academic performance, work productivity, and daily activities. The results of this study demonstrated that the EQ-5D-5L quality-of-life index in the Hoat Huyet Nhat Nhat group improved markedly from 0.52 ± 0.18 to 0.80 ± 0.18, whereas the placebo group showed a smaller increase from 0.51 ± 0.17 to 0.68 ± 0.19. The mean improvement was significantly greater in the study group than in the placebo group (0.27 ± 0.20 vs. 0.16 ± 0.20; $p < 0.01$). This finding reflects the comprehensive effect of the medication not only on pain symptoms but also on multiple aspects of physical health, mental well-being, self-care ability, and daily activities.

The study results showed that Hoat Huyet Nhat Nhat exerted a clear analgesic effect in patients with primary dysmenorrhea. Its mechanism of action may be explained from several perspectives. According to the ischemic theory, excessive uterine contractions reduce uterine perfusion, leading to tissue hypoxia and the accumulation of pain-inducing metabolites [3]. Herbs such as Angelica sinensis Radix, motherwort, Achyranthes root, Ligusticum chuanxiong, and red peony root have blood-activating, vasodilatory, and anticoagulant properties, which may improve circulation and reduce ischemia [7], [8]. Angelica sinensis has been demonstrated to activate blood circulation, improve pelvic blood flow, and relieve pain in gynecological disorders [9]. Ligusticum chuanxiong contains several bioactive compounds with vasodilatory, antiplatelet aggregation, and smooth-muscle antispasmodic effects, thereby reducing blood stasis and menstrual pain [10]. In addition, neuropsychological factors also play an important role in the pathogenesis of dysmenorrhea. Some experimental studies have shown that Angelica sinensis and Ligusticum chuanxiong may modulate the central nervous system, exert calming effects, and improve cerebral–uterine circulation, thereby contributing to pain reduction [9], [10], [11]. According to traditional medicine, primary dysmenorrhea mainly falls under the category of “thong kinh” and is caused by qi stagnation and blood stasis. The principle that “when qi moves, blood moves; when qi stagnates, blood stasis occurs” clearly explains the mechanism of pain when the circulation of qi and blood is impaired [4]. With its blood-activating and qi-regulating components, Hoat Huyet Nhat Nhat promotes the circulation of qi and blood, reduces stagnation, and thereby provides a comprehensive analgesic effect.

5. CONCLUSION

This study demonstrated that Hoat Huyet Nhat Nhat significantly reduced pain intensity and pain duration, while improving quality of life in patients with primary dysmenorrhea across traditional medicine syndrome patterns. It represents a safe and feasible non-pharmacological intervention for clinical practice. However, due to the small sample size and short follow-up period, further studies with larger sample sizes, controlled designs, and long-term follow-up are needed to confirm its effectiveness

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