The Comparative Effect of Herbal Extract of Vitagnus and Mefenamic Acid on
Primary Dysmenorrhea

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Abstract

Background: Dysmenorrhea is among the factors disrupting women's social activities. Selecting medicines with lower side effects are preferred. The objective of this study is to compare between the effect of herbal extracts of Vitagnus and Mefenamic Acid on the primary dysmenorrhea and menstrual bleeding in female students of the University of Medical Sciences, Hamadan in 2009-2010.

Materials and Methods: This Study was carried out on 80 students with primary dysmenorrhea as two-way blind clinical experience. The participants were randomly divided into three groups of receiving Vitagnus drop, Mefenamic Acid capsule, and placebo drop. Severity of dysmenorrhea was assessed using pain severity measurement tool during a cycle before and two cycle later taking the medicine. Data was analyzed using SPSS-16 Software.

Results: Individual characteristics of the samples were similar. Mean pain intensity and menstrual bleeding in a cycle before the treatment beginning had no significant differences in the three groups, but in two cycles after the treatment beginning, there was a significant difference between the three and the effect of Vitagnus drop was more effective than Mefenamic Acid capsule in mitigating dysmenorrhea (p=0.0001). The two medicines (mefenamic acid and Vitagnus) were effective in reducing menstrual bleeding (p<0.05).

Conclusion: Vitagnus drop and mefenamic acid resulted in mitigating dysmenorrhea and the effect of Vitagnus was more than mefenamic acid. The two medicines (mefenamic acid and Vitagnus) were effective in reducing menstrual bleeding. Accordingly, Vitagnus herbal medicine can be used as the effective and safe medicine for dysmenorrhea.

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Introduction

Dysmenorrhea is among the factors disrupting the quality of the young women's life and social activities especially with conditions such as headache, fatigue, vomit, diarrhea, moodiness, tremor and spasm [1-6]. Dysmenorrhea or painful menstruation is one of the common problems of women (50% to 70% women suffer from it). Usually, the pain begins a few hours before or simultaneously with menstrual bleeding and takes at last two or three days. Sometimes, the pains are distributed to waist, groin and legs, as well. The pain forces the individual to not to attend in her work or education place; namely, about 1% women in fertility ages are disrupted for three days a month. The problem leads to the waste of the millions of work hours in a year [7-10]. Also, the increase in the probability of the accidents and decrease of work quality in the individuals working despite their menstrual pain are significant [11]. Pain creation mechanism is assigned to the impact and activity of prostaglandins. Their concentration in women with dysmenorrhea is significantly higher than women without dysmenorrhea or weak dysmenorrhea. Light physical activities can mitigate the patients' complaints [10]. In the study of Zamin et al regarding the effect of mefenamic acid and vitagnus on reducing menstrual bleeding and hemoglobin changes in the patients with menorrhagia, both medicines (Mefenamic Acid and Vitagnus) induced a significant decrease in menstrual bleeding and hemoglobin increase in the patients [12]. Accordingly, there are various treatment methods and the selection of medicines with lower side effects is preferred. Taking Vitagnus popular as women plant in the world goes back to 2000 years ago. It affects pituitary-hypothalamus axis. Vitagnus increases LH production yet inhibits FSH production to some extent so a deviation will occur in the amount of estrogen to progesterone. The plant is used in treating infertility, menstrual disorders including PMS, dysmenorrhea, secondary amenorrhea, premenopausia disorders, and acne, fibrocystic of breasts as well as hyperprolactinemia [13]. Mefenamic acid is a
type of non-steroidal anti-inflammatory medicine used for mitigating pain and in particular menstrual and tooth pains. It has a half-life of two hours and is taken orally.

Materials and Methods

The study was carried out on 80 students with primary dysmenorrhea (ranging from average to severe) as two-way blind clinical experience in 2009-2010 in the University of Medical Sciences, Hamadan. The participants were randomly divided into three groups of receiving vitagnus drop, mefenamic acid capsule, and placebo drop. Severity of dysmenorrhea and menstrual bleeding level were respectively assessed using pain severity measurement tool and Higham Table during a cycle before and two cycle later taking the medicine.

Upon receiving the license from the Ethical Committee in Medical Studies, elementary questionnaire of primary dysmenorrhea severity determination measured using Visual Analogue Scale (VAS)) was structured and distributed among female students (to select statistical community of the study) and then 80 individuals with their primary dysmenorrhea ranging from average to severe (based on VAS, scored between 5 to 10) were selected.

The pain severity measurement tool includes a ruler with a length of 10cm scaled from 0 to 10 from the beginning to the end so that 0 indicates no pain and 10 the highest degree of the pain an individual might experience. This tool is standardized and its validity and reliability are proved in different studies [14]. Before administrating the medicine, the pain severity and menstrual bleeding level (based on Higham Table) were assessed in the units under study and the individuals were randomly and voluntarily divided in three groups of the study; group1: fasting reception of vitagnus drop (3-40ml a day [40 drops] in the morning with water before breakfast from a day before the beginning of menstruation to the third day of menstruation), group2: receiving Mefenamic Acid capsule (250mg each 8h from a day before the beginning of menstruation to the third day of menstruation) and group3: receiving placebo drop (30 drops each 4h from a day before the beginning of menstruation to the third day of menstruation). Data analysis procedure was descriptive statistics and the information gained was analyzed using SPSS-16 Software by One-Way ANOVA with the significance level p<0.05.

Results

Demographic features of the units under study are presented in table 1. As seen in table, the units had no statistically significant difference in the groups under study regarding the age, number of menstruation days, menstruation intervals and the age when they had their primary dysmenorrhea.

However, they had a statistically significant difference in their menarche age (p=0.02). Family conditions of dysmenorrhea, taking medicine in menstrual period, background of exercises and disruption in daily routine are represented in table 2 for the three groups under study.

In this study, the pain severity before beginning the treatment with vitagnus oral drop, Mefenamic Acid capsule and placebo drop were assessed in one cycle period (null cycle) with the mean pain severity of no significance at the end of the null cycle, but at the end of the first and second cycles (after interference or taking the medicine) was significant (p=0.001).

Here, mean pain severity was lower with vitagnus herbal medicine comparing to Mefenamic Acid or placebo. Results show that both medicines could mitigate the pain during the treatment (Table 3).

Vitagnus drop has shown statistically significant difference in mitigating the primary dysmenorrhea comparing to Mefenamic Acid capsule (p=0.0001) (Table 4).

Table 5 shows that both medicines (mefenamic acid and Vitagnus) are effective in reducing menstrual bleeding (p<0.05). Mefenamic acid capsule has not shown any statistically significant differences in reducing menstrual bleeding comparing to Vitagnus drop (p=1.00) (Table 6).

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Placebo</th>
<th>Vitagnus</th>
<th>Mefenamic Acid</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age(Year)</td>
<td>21.60±2.59</td>
<td>22.63±2.54</td>
<td>22.00±3.72</td>
<td>0.08</td>
</tr>
<tr>
<td>Menarche age(Year)</td>
<td>13.92±1.15</td>
<td>14.00±1.19</td>
<td>13.17±1.23</td>
<td>0.02</td>
</tr>
<tr>
<td>Menstrual cycle(day)</td>
<td>6.24±1.66</td>
<td>7.84±4.60</td>
<td>6.17±1.41</td>
<td>0.16</td>
</tr>
<tr>
<td>Interval (day)</td>
<td>27.36±3.63</td>
<td>26.52±5.43</td>
<td>27.03±3.81</td>
<td>0.19</td>
</tr>
<tr>
<td>First dysmenorrheal (Year)</td>
<td>16.16±1.81</td>
<td>15.76±2.00</td>
<td>15.50±2.71</td>
<td>0.17</td>
</tr>
</tbody>
</table>

Table 2. Distribution of absolute and relative frequency of some variables in the units under study

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Vitagnus</th>
<th>Mefenamic Acid</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Familial dysmenorrhea</td>
<td>Yes</td>
<td>17(68.0)</td>
<td>25(83.3)</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>8(32.0)</td>
<td>5(16.7)</td>
</tr>
<tr>
<td>Use of drug during menstruation</td>
<td>Yes</td>
<td>22(88.0)</td>
<td>24(80.0)</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>3(12.0)</td>
<td>6(20.0)</td>
</tr>
<tr>
<td>History of exercise</td>
<td>Yes</td>
<td>4(16.0)</td>
<td>7(23.3)</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>21(84.0)</td>
<td>23(76.7)</td>
</tr>
<tr>
<td>Interfere in daily work</td>
<td>Yes</td>
<td>17(68.0)</td>
<td>24(80.0)</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>8(32.0)</td>
<td>6(20.0)</td>
</tr>
</tbody>
</table>
Comparing between the first and second cycles

Mean and standard deviation of menstrual pain severity (cycles 0, 1 and 2) in the units under study based on the type of the medicine

<table>
<thead>
<tr>
<th>Drug</th>
<th>Vitagnus Mean±SD</th>
<th>Mefenamic Acid Mean±SD</th>
<th>Placebo Mean±SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cycle 0 (without drug)</td>
<td>5.8±1.3</td>
<td>5.6±1.9</td>
<td>5.1±1.4</td>
</tr>
<tr>
<td>Cycle 1 (with drug)</td>
<td>4.2±1.3</td>
<td>4.1±0.8</td>
<td>5.0±1.4</td>
</tr>
<tr>
<td>Cycle 2 (with drug)</td>
<td>3.2±1.7</td>
<td>3.6±1.7</td>
<td>4.1±1.3</td>
</tr>
<tr>
<td>p-Value</td>
<td>p=0.04</td>
<td>p=0.001</td>
<td>p=0.07</td>
</tr>
</tbody>
</table>

*p=0.05, p*: comparing between the three cycles, p*: comparing between the first and second cycles

Multivariate comparison of the medicines on menstrual pain severity (Bonferroni test)

<table>
<thead>
<tr>
<th>Group</th>
<th>Vitagnus Mean±SD</th>
<th>Mefenamic Acid Mean±SD</th>
<th>Placebo Mean±SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mefenamic Acid</td>
<td>0.30±0.5</td>
<td>0.0001</td>
<td>Placebo</td>
</tr>
<tr>
<td>Placebo</td>
<td>1.5±0.4</td>
<td>0.0001</td>
<td>Placebo</td>
</tr>
</tbody>
</table>

Table 5. Mean and standard deviation of menstrual bleeding (cycles 0, 1 and 2) in the units under study based on the type of the medicine

<table>
<thead>
<tr>
<th>Drug</th>
<th>Vitagnus Mean±SD</th>
<th>Mefenamic Acid Mean±SD</th>
<th>Placebo Mean±SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cycle 0 (without drug)</td>
<td>21.2±9.2</td>
<td>31.1±29.1</td>
<td>25.8±17.8</td>
</tr>
<tr>
<td>Cycle 1 (with drug)</td>
<td>11.2±28.9</td>
<td>16.1±21.7</td>
<td>24.8±14.9</td>
</tr>
<tr>
<td>Cycle 2 (with drug)</td>
<td>11.4±25.6</td>
<td>20.9±21.2</td>
<td>24.6±13.5</td>
</tr>
<tr>
<td>p-Value</td>
<td>p=0.02</td>
<td>p=0.0001</td>
<td>p=0.08</td>
</tr>
</tbody>
</table>

*p=0.05, p*: comparing between the three cycles, p*: comparing between the first and second cycles

Discussion

In the study, mean pain severity was lower with taking Vitagnus herbal medicine comparing to mefenamic acid or placebo. Results show that both medicines could mitigate the severity of pain. Also, they are effective in reducing menstrual bleeding. Acceptable theory regarding the cause of dysmenorrhea is the excessive production of endometrial prostaglandins; so the treatment must be designed to reduce the production of prostaglandins [13].

Since prostaglandins induce contraction, so using a medicine with anti-spasms quality can be useful in treating the pain and bleeding.

Here, severity of menstrual pain and bleeding were assessed before the treatment beginning (with oral drop of Vitagnus and mefenamic acid and placebo drop) for a cycle (null cycle) and mean pain severity and bleeding had no significant differences between the groups, yet significant at the end of the first and second cycles (after the intervention or taking the medicine). Results of the study demonstrate that both medicines could reduce the menstrual pain and bleeding during the treatment.

Other studies have also considered the effect of Vitagnus, Phenline and mefenamic acid on treating dysmenorrhea and menstrual bleeding as similar [12-16]. In the study of Nazarpoor et al regarding the effect of phenline and mefenamic acid on dysmenorrhea, the effect of phenline was no lower than mefenamic acid in mitigating the primary dysmenorrhea and can be useful in mitigating the pain severity and menstrual bleeding [17].

Results of the all studies on Vitagnus and mefenamic acid effects of mitigating the menstrual pain and bleeding correlated with present study. In the study, mean pain severity not only reduced at the end of the first month of the medicine administration, but also decreased the pain at the end of the second month and even decreased further as the time went by.

In the study of Shahhusseini et al regarding the effect of Vitagnus drop on dysmenorrhea, maximum medicinal effects were gained at the end of the third month. Here, it is also mentioned that at least three and at last six months or more are required to gain the acceptable effect of the medicine [18].

Vitagnus drop also showed statistically significant difference in reducing the primary dysmenorrhea comparing to mefenamic acid capsule. mefenamic acid has capsule showed no statistically significant difference in reducing menstrual bleeding comparing to Vitagnus drop, however, they both have been effective in reducing menstrual bleeding. Vitagnus herbal drop and mefenamic acid could decrease dysmenorrhea during the treatment with the higher effect of Vitagnus comparing to
mefenamic acid. Accordingly, Vitagnus medicine can be used as an effective and safe medicine in painful menstruation.

**Acknowledgements**

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**References**


