The effect of wheat germ extract on the severity of primary dysmenorrhea

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Abstract

Introduction:
Primary dysmenorrhea is one of the most common disorders in women, causing occupational dysfunction and school absenteeism. In view of the high prevalence of primary dysmenorrhea and its undesirable consequences on the quality of life, and due to the anti-inflammatory properties of wheat germ, this study was carried out to examine the effect of wheat germ extract on primary dysmenorrhea.

Material and methods:
The present study was conducted on 90 women employed at hospitals affiliated with Hamadan University of Medical Sciences using a triple blind controlled clinical trial method. The samples were divided into two 45-member groups; then, wheat germ extract 400 mg capsules or placebo was used three times a day for two consecutive months between the 16th day until the 5th day of the next menstrual cycle. The severity of the symptoms in each group and between the two groups was analyzed, respectively, with the Friedman and the Man-Whitney tests.

Results:
The severity of primary dysmenorrhea was alleviated in both groups after intervention. The alleviation was remarkably higher in the wheat germ extract group (p<0.001).

Conclusion:
The results of the present study confirm the positive effect of wheat germ extract on primary dysmenorrhea, showing that wheat germ extract can be used for easing the severity of primary dysmenorrhea.

Keywords: Dysmenorrhea, Complementary Medicine, Plant Extract

Introduction
Dysmenorrhea is a common gynecological disorder (1), and pathologically is divided into primary and secondary types. Primary dysmenorrhea is a painful menstruation in absence of any known pelvic condition in which cycles of pain begin in the lower abdomen a few hours before or after menstruation. Secondary dysmenorrhea is a painful menstruation with a known pelvic disease (2). Dysmenorrhea has mild, moderate, and intense severities. Mild dysmenorrhea means pain does not interfere with work and daily routine, and
does not need any pain killers. Moderate dysmenorrhea means pain slightly interferes with work and daily life and is reduced with intake of pain killers, and severe dysmenorrhea means pain interferes with normal activities (3). According to studies, 40% to 90% of women have dysmenorrhea (4), and in 10% symptoms can be so severe that interferes with work and causes absenteeism from school (5, 6). Several factors are involved in primary dysmenorrhea, and the most important is increased prostaglandin products (7, 8).

Various methods have been proposed to control and treat dysmenorrhea including topical heat, herbal remedies, thiamine, vitamin E, acetaminophen, aspirin, and contraceptive pills (1, 9). Herbal therapy is an ancient knowledge rooted deep in history (10). Herbal medicines are often safer, more effective and affordable alternatives to chemical drugs (11). Among herbal medicines, wheat germ contains a variety of minerals, vitamins and proteins in abundance, and according to analysis, wheat germ is composed of magnesium, zinc, calcium, sodium, potassium, phosphor, chromium, vitamin E, vitamin C, B12, B6, thiamine, riboflavin, niacin, folic acid, and iron (12, 14). Many studies have cited positive effects of some components of wheat germ (vitamin B6, Vitamin E, and vitamin B1) in reducing severity of dysmenorrhea. Positive effects of vitamins B6, E, and B1 in reducing severity of dysmenorrhea have been individually reported (1, 15, 16, and 17). Considering the presence of these vitamins in wheat germ, the present study was conducted with the aim to investigate the effect of wheat germ extract on primary dysmenorrhea.

**Material and methods**

This study was a triple-blind clinical trial conducted on 90 women employees of hospitals affiliated to Hamadan University of Medical Sciences. Study inclusion criteria were no known physical or mental diseases, no surgery or adverse events in the last 3 months, no known chronic pelvic diseases, and no use of contraceptives in the last 3 months. Events such as pregnancy or pain in the whole period led to exclusion from study. Data collection tool was a questionnaire, in which content validity was used for its validity and retest for its reliability (r=0.91). Reliability of the questionnaire has been demonstrated in several studies (18, 19). First, data forms 2 and 3 were completed, which related to recording maximum pain intensity during menstruation for 2 consecutive cycles. Intensity of pain was measured with Visual Analogue Scale (on a 10cm tape), in which, 1-3 indicate mild pain, 4-7, moderate pain, and 8-10 severe pain. Next, written consents were obtained from participants. Women were divided into two equal groups (45 in the case and 45 in the control groups) according to table of random numbers. To prepare capsules, extraction was carried out with ethanol 70% in 3 stages, each lasting 24 hours. After drying, resulting extract was milled, and encapsulated at School of Pharmacy of Shahid Beheshti University of Medical Sciences. Participants in the case group received three 400mg wheat germ extract capsules daily, and control group participants received three 400 mg placebo capsules with starch daily, from day 16 of menstruation cycle until day 5 of menstruation for 2 months. Forms 2 and 3 were completed by participants simultaneously with drug intake to determine intensity of pain. Questionnaires were collected after 2 months of intervention, and mean intensity of primary dysmenorrhea and associated systemic symptoms were calculated. Data were analyzed using SPSS-17 software. To compare intensity of pain and systemic symptoms between two groups, Mann-Whitney test was used, and to compare in-groups Friedman test was used, and if significant, Bonferroni correction was used for comparison in pairs.
Results

Of the initial 90 participants, 1 person due to pregnancy, 3 due to digestive problems, and 6 because of amnesia or inability to correctly use capsules were excluded from study. Demographic characteristics are presented in table 1.

According to independent T-test results, there was insignificant difference between the two groups before intervention in terms of age, BMI, income, education, and spouse’s education, age at menarche and at marriage. Furthermore, there was an insignificant difference between two groups in terms of mean intensity of primary dysmenorrhea and mean number of analgesics taken. According to Friedman test, mean intensity of primary dysmenorrhea, two months after intervention, was significantly reduced in the group that used wheat germ extract (P<0.001), but in the placebo group the difference was insignificant (P=0.203) (table 2). According chi-square results, 95.2% of wheat germ group and 92.9% in placebo group reported no side-effects, and the difference between them was insignificant (P=0.556).

<table>
<thead>
<tr>
<th>Variables</th>
<th>Wheat germ extract</th>
<th>Placebo</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>33.45±5.89</td>
<td>32.84±5.58</td>
<td>0.637</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>59.16±9.52</td>
<td>61.82±6.92</td>
<td>0.781</td>
</tr>
<tr>
<td>BMI (kg/m2)</td>
<td>23.43±1.86</td>
<td>23.02±1.88</td>
<td>0.328</td>
</tr>
<tr>
<td>Duration of menstruation cycle</td>
<td>27±2.81</td>
<td>28.02±2.07</td>
<td>0.348</td>
</tr>
<tr>
<td>Age at menarche</td>
<td>13.57±1.48</td>
<td>13.92±1.44</td>
<td>0.289</td>
</tr>
<tr>
<td>Marital status</td>
<td>Married 71.4%</td>
<td>Married 76.3%</td>
<td>0.625</td>
</tr>
<tr>
<td>Single 28.6%</td>
<td>Single 23.7%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 2: Comparison of mean intensity of primary dysmenorrhea before and after intervention in the two groups

<table>
<thead>
<tr>
<th>Groups</th>
<th>Before intervention</th>
<th>4 weeks after intervention</th>
<th>8 weeks after intervention</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wheat germ extract</td>
<td>4.70±2.87</td>
<td>2.32±1.92</td>
<td>1.12±1.50</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td>Placebo</td>
<td>5.07±3.01</td>
<td>3.99±3.31</td>
<td>3.81±3.42</td>
<td>P=0.203</td>
</tr>
<tr>
<td>P-value</td>
<td>0.509</td>
<td>0.04</td>
<td>0.003</td>
<td></td>
</tr>
</tbody>
</table>

Mann-Whitney
Freidman - Bonferroni correction

Discussion

Study results showed that wheat germ extract significantly reduces intensity of primary dysmenorrhea (P<0.001). Wheat germ uses pro-inflammatory activities to activate neuropeptides, cytokines, and macrophages to reduce inflammation in two weeks. Furthermore, daily intake of 20 ml to 100 ml of wheat germ extract reduces ulcerative colitis and associated symptoms by 78%, including abdominal pain (12), which agrees with present study results. Wheat has anti-inflammatory properties and improves blood circulation, eliminates blood stasis, and reduces pain (20). No study has directly investigated the effect of wheat germ on dysmenorrhea. However, positive effects of some wheat germ compositions including thiamine, pyridoxine, magnesium, and vitamin E on dysmenorrhea have been mentioned (1), which explains the present study results. Vitamin B12 in wheat germ acts as an antioxidant and reduces prostaglandins and leukotrienes, resulting in reduced pain. The positive effect of omega-3 with vitamin B12 in reducing menstruation pains is known (21), which is in line with the present study results. The similarity in findings may be due to vitamin B12 in wheat germ. Wheat germ is full of vitamin E, which is an antioxidant that can prevent...
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oxidation of arachidonic acid and production of prostaglandins (16) and reduce dysmenorrhea. Benefits of twice daily intake of 200 units of vitamin E in reducing intensity and duration of primary dysmenorrhea have been demonstrated (22). Also, combined use of mefenamic acid and vitamin E causes greater reduction in dysmenorrhea than mefenamic acid alone (23). The similarity in results with the present study may be due to vitamin E in wheat germ. Wheat germ contains magnesium, which reduces prostaglandin F2α and muscle contraction (24). Daily intake of 300000 IU/1ml of vitamin D, 5 days before menstruation, reduces intensity of dysmenorrhea pain (25), which agrees with present study findings, and the similarity may be due to the effect of vitamin D in wheat germ.

Wheat germ also contains vitamin B1. Positive effect of daily intake of 100 mg of vitamin B1 for 3 consecutive cycles in reducing intensity of pain has been cited, which has the same effect as Ibuprofen 400 mg, without any particular side-effect (26). Wheat germ contains magnesium, and positive effect of 3 times daily intake of 4.5 mg magnesium 7 days before menstruation to 3 days after in reducing intensity of dysmenorrhea has been demonstrated (24). Also, wheat germ is full of calcium and benefits of calcium in reducing cramp and pain has been mentioned (27).

Two months after intervention, mean number of analgesics used was only reduced in wheat germ group (P<0.001), and no significant difference was observed in placebo group.

Four times daily intake of 100 units of vitamin E for 3 consecutive days reduces intake of analgesics (28), which agrees with present study results. This similarity in results may be due to the presence of vitamin E in wheat germ. There was no significant difference between two groups in terms of side-effects. According to the present study, no particular side-effect can be attributed to wheat germ. The present study results demonstrate effectiveness and safety of daily intake of 1200 mg wheat germ extract in reducing primary dysmenorrhea. Padalia et al. in their review study on benefits of wheat germ extract confirmed lack of side-effects in daily use of wheat germ (29), which concurs with present study results.

Conclusion

Use of wheat germ extract can reduce intensity of primary dysmenorrhea, which can be explained by the presence of vitamin B6, vitamin E, calcium, vitamin B1, and magnesium in wheat germ as demonstrated in previous studies. Furthermore, wheat germ extract has no side-effect, and it seems it can be used to reduce intensity of primary dysmenorrhea.

Acknowledgements

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