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The impact of extra virgin olive oil on primary dysmenorrhea in comparison to the ibuprofen

Maryam Rezaeyan[1], Parichehr Khedri[1], Narges Abdali[2] and Ashraf, Direkvand-Moghadam[3]

[1]Faculty of Nursing and Midwifery, Islamic Azad University Branch of Borujerd, Lorestan, Iran
[2]Razi Herbal Medicines Research Center, Lorestan University of Medical Sciences, Lorestan, Iran
[3]Psychosocial Injuries Research Center, Faculty of Nursing and Midwifery, Ilam University of Medical Sciences, Ilam, Iran

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ABSTRACT

The chemical treatments of primary dysmenorrhea have some side effects. Therefore, the present study was conducted to compare the efficacy of Extra Virgin olive oil and Ibuprofen for treatment of primary dysmenorrhea among female students. Materials and Methods: In a single blinded crossover clinical trial, female single students 17-30 years old, moderate and sever primary dysmenorrhea were enrolled to the study. Chronic disease, allergies, pelvic or abdominal surgery, stressors in the past two months, irregular menstrual cycles, use of oral contraceptives during 3 months ago were excluded from the study. Screening for primary dysmenorrhea was done by a visual analog scale.Participants were randomly divided into two groups. The participants were followed up for 5 menstruation cycles. The subjects in group 1 took 25 cc of extra virgin olive oil daily for 2 months (starting two weeks before the start of the menstruation cycle) and completed a questionnaire containing items on pain visual analogue scale for two consecutive cycles. After a 4-week washout period they received 400 mg Ibuprofen three times a day in the first 3 days of menstruation. Group 2 was treated basically similarly, except that they received Ibuprofen during the two first cycle and extra virgin olive oil during the two second cycle. The collected data were analyzed using the descriptive and inferential statistics, t-test and linear mixed models. The pain severity difference was significant before and after intervention in both groups. The pain severity decreased to 3.8 ± 2.2 after intervention in Ibuprofen group and 1.1 ± 0.8 after intervention in Extra Virgin olive oil group. There was a significant difference in pain severity between the two groups after the intervention (P= 0.001). The Extra Virgin olive oil is effective in primary dysmenorrhea. It is recommended as a food supplement.

Key words: Crossover clinical trial, Food supplement, NSAIDs

INTRODUCTION

Primary dysmenorrhea is defined as severe uterine pain during menstruation (1). It´s prevalence is ranging 25% - 90%. Primary dysmenorrhea is common in teenage years and less seen among women after the 20-25 years old (2). Dysmenorrhea always been an important issue in terms of socio – economic. It is estimated that the primary dysmenorrhea is the biggest cause of loss of work time and school. In addition to the economic problems, the primary dysmenorrhea also affect females social relationships (3).

Prostaglandins are produced in the endometrial and cause uterine contractions. On the other hand, the primary dysmenorrhea is caused as a result of the secretary endometrial (4).

(5)are several medical and non medical treatments (1-3, 6-8). Non-steroidal anti-inflammatory drugs (NSAIDs) are consider as the most common medical treatments among women who are suffering from the primary dysmenorrhea. NSAIDs can reducing the uterine contractions (1, 9). Oral contraceptive pills (OCPs) has been applied as treatments for the primary dysmenorrhea. Although recent studies have rejected the use of this method in the treatment of primary dysmenorrhea (10, 11).

Given that most medical treatment of primary dysmenorrhea have risks for their consumers, thus the use of non-pharmacological treatment of dysmenorrhea is considered (1, 2). Hence, the used of the herbs treatment for the primary dysmenorrhea has an universal application. Recently, the Extra Virgin olive oil is considered for its anti-inflammatory effect (12). Although we not found study on the impact of Extra Virgin olive oil on primary dysmenorrhea, several studies have been evaluated the effects of Extra Virgin olive oil on the coronary artery inflammation (13), hypertension (14), colon cancer (15) and arthritis . These studies have confirmed the effectiveness and safety of Extra Virgin olive oil.

The chemical treatments of primary dysmenorrhea have some side effects, on the other hand, consumers tend to apply non-pharmaceutical techniques and dietary supplements in the treatment of primary dysmenorrhea. Therefore, the present study was conducted to compare the efficacy of Extra Virgin olive oil as a new non-pharmaceutical techniques and Ibuprofen as the most useful pharmaceutical techniques for the treatment of primary dysmenorrhea among university female students of Islamic Azad University Branch of Boroujerd, Iran during 2011.

MATERIAL AND METHODS

This study was a single blinded, crossover clinical trial that was conducted in 2011. Considering the power of 80% and α=5%, 28 participants were required for each group. Because of the loss of samples during follow up, 30 participants were selected for each group. Random sampling method was carried out and subjects were randomly assigned to two groups as they did in previous randomized studies (2, 16).

Female single students, with 17-30 years old, moderate and sever primary dysmenorrhea (pain severity more than 4 according to the VAS scoring) who accommodated at the campus of Islamic Azad University Branch of Boroujerd were enrolled to the study.

All participants with chronic disease including kidney disease, pulmonary, cardiovascular, gastrointestinal, endocrine and metabolic, allergies to olive and olive oil and Non-steroidal anti-inflammatory drug, pelvic or abdominal surgery, stressors such as the death of relatives or others in the past two months, irregular menstrual cycles with intervals less than 21 – and more than 35 days over the past year, use of oral contraceptives during 3 months ago were excluded from the study.

Participants visited physically by a licensed gynecologist and rollout the pathological disorders before randomization. All eligible participants fulfilled the self-completed questionnaire. A two parts questionnaire was used to data collection. The first part of questioner as demographic part was included the menstrual history, smoking, diet, exercise and past medical and reproductive history that was completed before the intervention of the trial. The second part of questioner part was designed to cover the severity and duration of pain and completed during the follow up of the study. The primary outcome was the pain severity, which was determined by the Visual Analogue Scale (VAS) in ranging 0-10, including without pain: 0-1, mild: 2-4, moderate: 5-6, severe: 7-8 and very severe: 9-10. The validity and reliability of these instrument has been confirmed in an Iranian study (17).

In general, participants were evaluated during 6 periods. The first period was a screening period. In fact, this month was includes periods prior to any intervention. After initial screening and identify individuals eligible for the study, 60 participants were randomly divided into two groups.The participants were followed up for 5 menstruation cycles. The participants in group 1 took 25 cc of Extra Virgin Olive oil daily for 2 months (starting two weeks before the start of the menstruation cycle) and completed a questionnaire containing items on pain Visual Analogue Scale for two consecutive cycles. After a 4-week washout period they received 400 mg Ibuprofen three times a day in the first 3 days of menstruation. Group 2 was treated basically similarly, except that they received Ibuprofen during the two first cycle and Extra Virgin Olive oil during the two second cycle. The pain severity during the first three days of each menstruation period was recorded similar in both groups. During the study, if the participants did not follow

the treatment protocol such as the need for additional medication use, non-use of olive oil as instructed or unwillingness to continue the research were excluded from the study.

This study was undertaken with the approval of the Ethical Committee of the Islamic Azad University Branch of Boroujerd. The participation in the study was voluntary and the participants were free to withdraw from the study whenever they wished. An informed consent was obtained from all participants before the enrolment to the study. This study is registered at the IRCT: IRCT2013051110804N2.

The collected data were entered into SPSS 16. Then were analyzed using the descriptive and inferential statistics, t-test and linear mixed models. However this are Cross Over data, have not the condition of independence. therefore a linear mixed model was used to analyze the data. A p-value of 0.05 was considered statistically significant.

RESULTS

A total 60 female university student subjects were randomly assigned to two groups Extra Virgin olive oil group and Ibuprofen group. The CONSORT Flow Diagram for study participants are presented in figure 1.

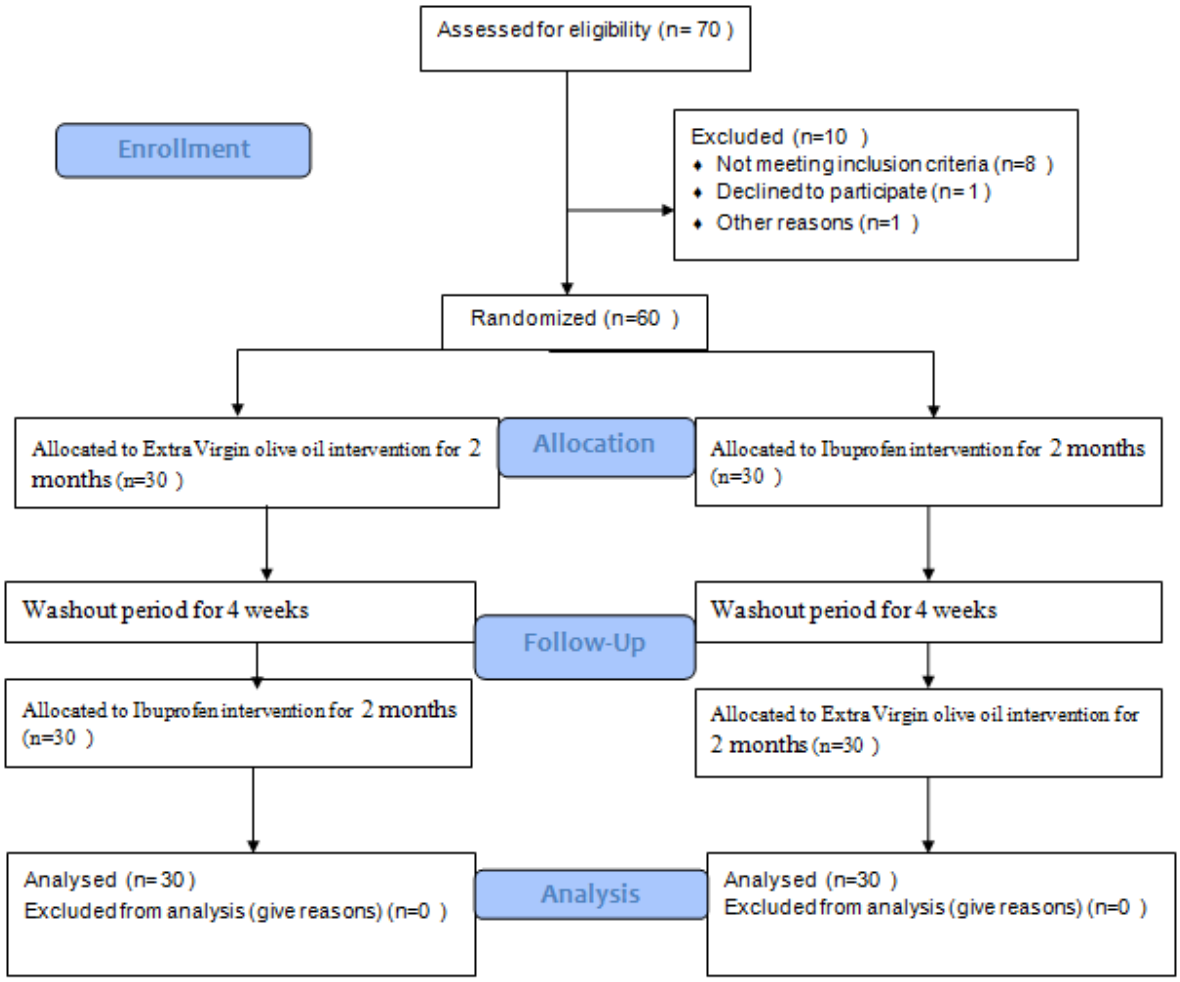

Figure 1. The allocation and follow-up of participants in the study

The Mean ± SD participants age was 22.35 ± 2.3. The Mean ± SD menarche age was 13.1 ± 0.85 among study's participants. The Mean ± SD age of start dysmenorrhea was reported 13.5 ± 0.98. No significant difference was

observed for the matched participants' characteristics at the time of allocation. The participants' characteristics are presented in Table 1.

Table 1. Comparison of the participants' characteristics at the time of allocation

Characteristic	Group		P- value
	Extra Virgin olive oil *	Ibuprofen*	
Age	21.86 ± 2.35	22.86 ± 2.35	0.12
Age of start dysmenorrhea	12.86 ± 0.86	13.33 ± 0.79	0.18
Duration of menstrual flow	4.7 ± 1.5	4.5 ± 1.5	0.34
Wight	59.86 ± 6.35	58.16 ± 6.35	0.54

** Mean ± SD*

Using mixed linear models, the pain scores were compared before and during intervention in both groups. However, there wasn't a significant difference in pain severity before interventions between the two groups, but also, the difference of pain severity was significant between the groups during the interventions. In general, the interventions have been effective whit a decreasing trend. Also there wasn't interaction sequence of interventions (beginning Ibuprofen or Extra Virgin olive oil).

Before the intervention, Mean ± SD of pain severity was 6.7 ± 1.7. However, the pain severity decreased to 3.8 ± 2.2 after intervention in Ibuprofen group and 1.1 ± 0.8 after intervention in Extra Virgin olive oil group. The pain severity difference was significant before and after intervention in both groups. Also there was a significant difference in pain severity between the two groups after the intervention (P= 0.001). In the Ibuprofen group, the Mean ± SD of pain severity was 4.7 ± 2.3 and 3.8 ± 2.2 during the first and second months of intervention, respectively. However, in the Extra Virgin olive oil group, the Mean ± SD of pain severity was 2.4± 1.7 and 1.3 ± 1.2 during the first and second months of intervention, respectively(P= 0.001).

DISCUSSION

Women's health is an important issue. So far studies have investigated different aspects of women's lives and the factors affecting it (18-24). The results of present study showed that the consumption of both Ibuprofen and Extra Virgin olive oil are effective in reducing pain of primary dysmenorrhea. It well been known that the release of prostaglandins and subsequent contraction of the myometrium caused the primary dysmenorrhea. Thus, inhibitors the release of prostaglandins are the first line treatment of primary dysmenorrhea (2). Although we did not find any studies on the impact on primary dysmenorrhea, but anti-inflammatory properties of this substance has been confirmed in previous studies in other inflammatory diseases (13-15, 25). Extra virgin olive oil contains a compound called Oleocanthal that suppresses the prostaglandins production. In other words, the Oleocanthal inhibit the enzymatic pathway which NSAIDs such as Ibuprofen make it inactive. Although the chemical structure of the Oleocanthal is different from the anti-inflammatory compounds in the NSAIDs, but the effect of Oleocanthal is similar to the anti-inflammatory compounds in the NSAIDs (12, 26). Use olive oil as a fixed component of the diet, can prevent inflammatory diseases. So we can say that consumers benefit from anti-inflammatory properties of Olive oil, as well as long-term use of Ibuprofen. it is important to use the appropriate amount of Olive oil is any risk for consumers. Although the risk of gastrointestinal bleeding and kidney damage are common among consumers with prolonged use of non-steroidal drugs such as Ibuprofen (13).

Other findings of present study showed the that Mean ± SD pain severity has been reduced in the second month of intervention. the pain severity reduced has been more in the Extra Virgin olive oil group than Ibuprofen group. Probably the gradual effect, enhances the effect during the second month of intervention. This result is consistent with previous findings about supplements is the primary dysmenorrhea (4, 7). An Iranian study reported that if the Mean of pain severity of primary dysmenorrhea reduced to three units, then the pain reduction is clinically significant (27). In the Ibuprofen group reported a clinically significant reduction of pain severity in the second month of the intervention. While in the Extra Virgin olive oil group this reduction has happened in the first month of the intervention. Probably the difference between consumption of these two interventions is the reason of difference. Limitations of this study include: lack of assessment the impact of Extra Virgin olive oil and Ibuprofen on other symptoms of primary dysmenorrhea. This was a single-blind study and all participants were aware of the type of intervention, the lack of control calories from Olive oil consumers.

CONCLUSION

The study showed that the consumption of Extra Virgin olive oil is effective in primary dysmenorrhea. Because of complications associated with non-steroidal anti-inflammatory drug, the use of Extra Virgin olive oil is seems as an appropriate alternative. Therefore, used of the Extra Virgin olive oil is recommended as a food supplement.

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