Cukurova Medical Journal
ÇUKUROVA ÜNİVERSİTESİ TIP FAKÜLTESİ

Cukurova Med J 2019;44(Suppl 1):54-60
DOI: 10.17826/cumj.550663

ARAŞTIRMA / RESEARCH

Effects of foot reflexology on dysmenorrhea: a randomized controlled trial

Ayak refleksolojisinin dismenore üzerine etkileri: randomize kontrollü bir çalışma

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Cukurova Medical Journal 2019;44(Suppl 1):54-60.

Abstract

Purpose: The present study aimed to determine the effects of foot reflexology on dysmenorrhea.

Materials and Methods: A randomize controlled trial design was used. This study included 29 student is in the intervention, 29 student in placebo groups. In the reflexology group, the subjects received 8 reflexology sessions (30 minutes each) in two consecutive mense cycles. The placebo groups , the subjects received 8 foot massage sessions (30 minutes each) in two consecutive mense cycles. To assess the severity of dysmenorrhea, Visual Anolog Scala and Verbal category scale were used in this study.

Results: When VAS mean scores of the experimental and placebo groups during 4 follow-up periods were compared, it was found that there is not a statistically significant difference between experimental and placebo groups.

Conclusion: Results showed that reflexology and placebo foot massage might be effective in decreasing dysmenorrhea. It is recommended that the students suffering from dysmenorrhea problems should be informed on the foot and reflexology massage.

Keywords: Dysmenorrhea, foot massage, reflexology massage

Öz

Amaç: Bu çalışma ayak refleksolojinin dismenore üzerine etkisini belirlemek amacıyla yapılmıştır.

Gereç ve Yöntem: Randomize kontrollü çalışma dızaynı kullanılmıştır. Bu çalışmada 29 öğrenci müdahale grubunda, 29 öğrenci placebo grubunda yer almıştır. Refleksoloji grubu, birbirini izleyen iki menstrual siklus 8 refleksoloji oturumu (her biri 30 dakika) yapılmıştır. Plasebo grubu ise birbirini izleyen iki mentrual siklus 8 ayak masajı oturumu (her biri 30 dakika) yapılmıştır. Bu çalışmada dismenorenin şiddeti Visual Analog Skala ve Sözel Kategori Ölçeği ile değerlendirilmiştir.

Bulgular: Dört izlem periyodunda deney ve placebo grubu karşılaştırıldığında gruplar arasında istatistiksel olarak fark olmadığı bulunmuştur.

Sonuç: Çalışmanın sonuçları refleksoloji ve plasebo ayak masajının dismenoeyi azaltmada etkili olduğunu göstermektedir. Dismenore problem olan öğrencilere ayak ve refleksoloji masajı hakkında bilgilendirme yapılması önerilebilir.

Anahtar kelimeler: Dismenore,Ayak masajı,refleksoloji masajı

INTRODUCTION

Dysmenorrhea is the most common cyclic pelvic pain[1]. The prevalence of dysmenorrhea has been reported as 50-90%[2-5]. Dysmenorrhea is classified as primary and secondary dysmenorrhea. The former one is more common among adolescents[6]. Primary dysmenorrhea is defined as the intermittent cramping pain in the lower abdomen. It may be local or may spread to the back, waist, groin and vulva[7]. This pain is periodic and often causes headaches, emotional disorders, stroke and gastrointestinal (GI) tract problems such as nausea, vomiting and frequent defecation[8]. Symptoms last 6 to 72 hours and are accompanied with sweating, headaches, and decline

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Geliş tarihi/Received: 08.04.2019 Kabul tarihi/Accepted: 04.05.2019 Çevrimiçi yayın/Published online: 23.09.2019

in concentration, fainting, loss of appetite, diarrhea and fatigue [9].

Primary dysmenorrhea can be treated pharmacologically, non-pharmacologically or surgically. The first step in the treatment of primary dysmenorrhea is the management of prostaglandin synthesis inhibitors. Contractions of the uterus, pain and discomfort decrease in parallel with the decreases in the synthesis of prostaglandin. Non-steroidal anti-inflammatory drugs (NSAIDs) provide partial pain relief. However, the constant use of NSAIDs can lead to problems related to kidney function and GI tract[10]. Instead of NSAIDs, complementary / supportive treatments can be used. In several studies, herbal mixtures, transcutaneous electrical nerve stimulation (TENS), acupuncture, acupressure, heat application, increased physical activity, low-dose vegetarian diet, omega-3 supplementation, reflexology and massage have been reported to be effective on dysmenorrhea[11,12]. Reflexology is the stimulation of reflex pressure points on the hands and feet through massage. These pressure points are considered a small mirror of specific organs of the body. With this method, the self-repair mechanism of the body is activated, which provides a physiological relaxation in the body. Reflexology can also maintains homeostasis and strengthens the immune system by accelerating blood flow[13,14]. While our search for studies investigating the effect of reflexology on dysmenorrhea demonstrated a gap in Turkish literature, two studies conducted abroad reported that reflexology reduced the symptoms of dysmenorrhea[15,16].

The aim of this study was to evaluate the effect of reflexology on dysmenorrhea. The following hypotheses (H) were tested in this study:

- H0: Foot reflexology has not an effect on reducing dysmenorrhea.
- H1: Foot reflexology has an effect on reducing dysmenorrhea.

MATERIALS AND METHODS

The study population composed of 192 nursing student. The student included in study was instructed to fill out the Dysmenorrhea Diagnostic Form in order to investigated the status of their dysmenorrhea experiences. After the implementation of form, 91 student experinces dysmenorrhea (those who scored above 5 on the visual analog scale) 62 of which inclusion criteria of study (Figure 1). Power analysis performed to estimate the individual size of the experimental and placebo groups suggested each group include at least 30 subjects (Alfa (α) = 0.05, power (1-β) = 0.90, the standard deviation %10). Sixtytwo people were randomly divided into two groups.

Before the study was conducted, approvals were obtained from Erciyes University Clinical Research Ethics Committee indicating that there was no ethical or scientific objection to conducting the study (2013/351). Before the study was conducted, the students to participate in the study were told that the participation was voluntary and that their credentials would be kept confidential. Then their written informed consent was obtained.

Study population

Of the students, those who met the following inclusion criteria were randomly assigned to the experimental group and placebo group: being healthy, nulliparous and not using hormonal contraceptives or an intrauterine device (IUD), having had regular menstruation during the last 6 months, obtaining a score of ≥5 from the Visual Analog Scala, having wound problems with neither foot, volunteering to participate in the study and signing the informed consent form. Having a gynecological disease, having a systemic chronic illness, not willing to participate in the reflexology and nonspecific food massage sessions.

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The study was carried out with a single-blind, randomized controlled trial research method. The student who participated in the study were blinded to their assignment to either the intervention group or in the placebo group. All phases of this study were designed based on the Consolidated Standards of Reporting Trials (CONSORT).

Before the intervention, the participants, based on their VAS scores, were randomly assigned to the reflexology and placebo groups through coin flipping. After massage interventions were started, a

student who developed a follicular cyst during the first session and three students who did not attend the second session were excluded from the study, and the study was completed with 58 students, (29 in the reflexology group and 29 in the placebo group). The power of the study was calculated as 99.4% with the power analysis. (Figure 1).

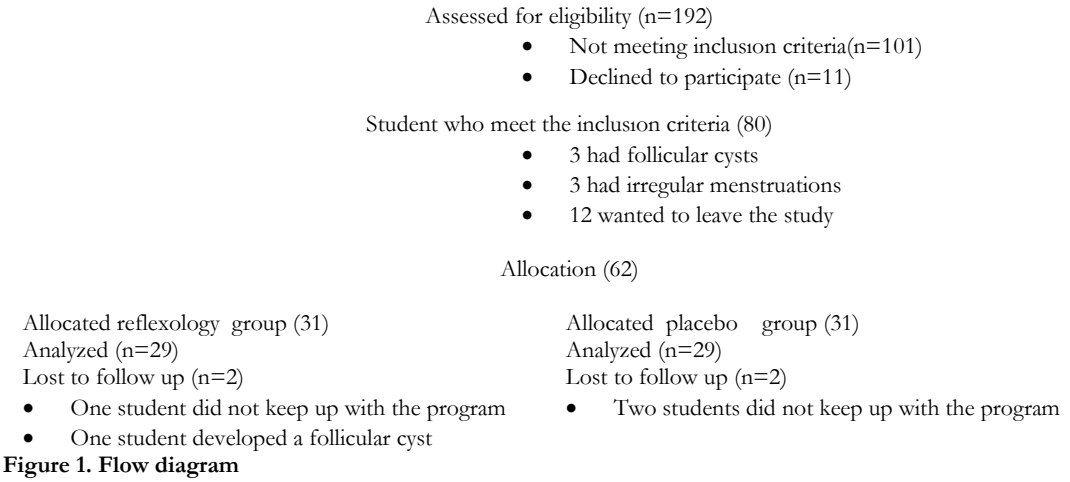

Figure 1. Flow diagram

Intervention

The experimental and placebo group were followed two cycles without any intervention. The student who met inclusıon of study were assigned two groups. The experimental group in this study received precision reflexology treatment, while the placebo group received nonspecific foot massage to find out whether the pressure applied to specific points or nonspecific foot massage had an effect on dysmenorrhea.

In order to reduce the effects of environmental factors and possible other factors (such as relaxation) that might affect the results of the study, standard therapy was administered to the students in both groups. To establish this standard, the researcher built the 14-item reflexology protocol and a 10-item non-specific food massage protocol. The participants were administered no treatment other than foot massage and reflexology massage. The participants were not informed about the randomization of the groups.

In the present study, both the reflexology massage and the placebo foot massage were performed by the researcher. The researcher received a five-day practical training on the dysmenorrhea areas prior to the application of reflexology and she was given a certificate. After receiving the certificate, the researcher implemented what she learned at the training five women with dysmenorrhea problems and improved her skills.

Table 1. Demographic characteristics of students

Characteristics	RG (n=29)	PG (n=29)	p
Age (mean±SD,yrs)	20.3±1.2	19.8±1.5	0.131
Age of menarche (mean± SD, years)	13.5±1.2	13.4±1.1	0.91
Smoking [n(%)]			
Smokers	3 (10.3)	2 (6.9)	0.64
Nonsmokers	26 (89.7)	27 (93.1)	

RG:Reflexology Group; PG :Placebo Group

Reflexology and foot massage were administered in two menstrual cycles during the premenstrual period. Reflexology and placebo foot massage were performed four times every other day during the last ten days of the cycle. During the two menstrual cycles, 8 sessions were held. Each session lasted 30 minutes.

In the reflexology group, points in each foot corresponding to the hypophysis, brain hypothalamus, spinal cord, uterus, ovaries and fallopian tubes were massaged.

In placebo groups, also called as the foot massages group, the eyes, ears and outside of the foot were

massaged. During the placebo massage, to prevent messages to reach the relevant organs, heat application, part of the reflexology massage was not performed.

Measures

Dysmenorrhea Diagnostic Form (DDF)

The form was developed by the researcher through a literature review to detect the presence of dysmenorrhea and some characteristics of the students to be included in the study group .The items of the DDF question students' age, marital status, chronic diseases and allergies, gynecological and obstetric histories, use of contraceptive methods, menstrual characteristics, menstruation problems, severity of dysmenorrhea

Visual Analogue Scale (VAS)

Pain intensity was measured with the VAS. The VAS is used to measure the subjectively perceived pain. The scale has a line 10 centimeters (100 mm) in length used to determine the intensity of the pain quantitatively. The left end of the line is marked "0" and refers to "no pain". The right end is marked "10" (in cm) or "100" (in mm) and refers to "very severe pain" [17]. The individual / patient marks the intensity level of his/her pain on the line. This marked line is used as numeric data for determining the level of pain perception.

The scale is easy to understand. The VAS has been used in studies conducted to assess the intensity of primary dysmenorrhea and is accepted as a reliable and valid instrument. [18-24]. In the present study, the students were asked to write down the intensity of the pain as a numerical value in the DFF when the pain first began.

Verbal Category Scale (VCS)

The verbal category scale is also called a simple descriptive scale. The scale is based on the most appropriate words the individual / patient uses to describe the intensity of his/her pain. The intensity of pain ranges from no pain to unbearable pain, and the person is asked to choose one of these categories which best matches his/her pain level[18].

Statistical analysis

Data were entered into SPSS statistical software (v. 16). To find out whether the data were normally distributed, the Shapiro-Wilk normality test was used. To display the demographic features of the students, the statistics such as numbers, frequency, mean, and standard deviation were used. Continuous variables were expressed as mean and standard deviation (SD). Continuous variables such as the mean VAS scores were compared using the independent sample t-test. Categorical variables such as Verbal Category Scale were compared using Chisquare test. Each menstrual cycle was evaluated by itself; they were not compared with each other. In all the comparisons, α level of <0.05 was considered significant

RESULTS

The distribution of the students in the reflexology group (RG) and placebo group (PG) in terms of age, age at menarche and smoking status is given in Table 1. The mean age of the students was 20.3 years in the reflexology group and 19.7 years in the placebo group. The mean age at menarche was 13 years in both groups. The characteristics of the students in both groups regarding age, age at menarche and smoking status were similar (p> 0.05) (Table 1).

Table 2. Comparison of the mean scores of dysmenorrhea in two group

	Before intervention	After intervention		
	mean±SD/mean (Min-Max)	mean±SD/mean (Min-Max)		
VAS	1st follow up	1st period	2nd period	3rd period
RG (n=29)	7.0±2.0/ 7(3-10)	4.9±2.8/ 5 (0-10)	3.4±2.6/4(0-9)	3.8±2.9/4 (0-10)
PG (n=29)	7.6±1.9 / 7(4-10)	4.7±2.7 /5(0-10)	3.9±2.4/4(0-8)	3.2±2.6/3(0-8)
p	0.230	0.706	0.407	0.451

VAS:Visual Analog Scale; RG:Reflexology Group; PG :Placebo Group

The distribution of VAS scores of the students in the reflexology and placebo groups in terms before intervention and intervention periods is given in Table 2. The mean VAS scores of the students in the reflexology group in the before intervention period were 7 (p>0.05). The mean VAS scores of the

students in the control group in the before intervention were 7 and almost the same as those of the students in the reflexology group. There was not a difference between the groups in terms of their mean VAS scores obtained during the intervention period.

Table 3. Comparison of VCS in two groups

	RG				PG				
VCS	No pain	Moderate	Severe	Very severe	No pain	Moderate	Severe	Very severe	p
Before intervention	0.00	3.4	41.4	55.2	0.00	0.00	31.0	69.0	0.392
1st period	3.4	27.6	51.7	17.2	3.4	10.3	69.0	17.2	0.394
2nd period	20.7	13.8	58.6	6.9	3.4	34.5	44.8	17.2	0.047
3rd period	13.8	31.0	41.4	13.8	10.3	34.5	44.8	10.3	0.945

VCS: Verbal Category Scale; RG:Reflexology Group; PG :Placebo Group

The distribution of the pain intensity levels described by the students in the reflexology and placebo groups according to the Verbal Category Scale during before intervention and intervention periods is given in Table 3. Before intervention period, approximately half of the students in the RG 55,2% and two-thirds of the students in the PG 69 % described their pain level as very severe.

After the intervention, almost half of the students both in the RG (17,2% in the 1st month, 6,9 % in the 2nd month and 13,8 % in the 3rd month) and in the PG (17,2% in the 1st month, 17,2 % in the 2nd month and 10,2 in the 3rd month) described their pain level as severe. There was no statistically significant difference between pain descriptions of the two groups during the intervention period ($p > 0.05$). During the control month when no massage was applied, the intensity of pain began to rise again

DISCUSSION

Primary dysmenorrhea is an important health problem that negatively affects women during premenstrual and menstrual periods[9]. Complementary / supportive therapies are reported to be effective on dysmenorrhea and to decrease the symptoms of dysmenorrhea significantly [22] There is a small body of research conducted on the impact of reflexology on dysmenorrhea[15,16,23]. Because our search for studies conducted on this issue demonstrated a gap in Turkish literature, this present study was intended to find out the effects of reflexology on dysmenorrhea, and the results obtained were discussed in the light of international literature. The intensity of pain which was high and similar among students both in the RG and in the PG before intervention period prior to the interventions at the onset of dysmenorrhea decreased during the intervention period. Especially in the second menstrual cycle, it decreased by half (Table 2).

In studies in which complementary / supportive therapies were implemented to alleviate the symptoms of dysmenorrhea, VAS scores measured prior to the intervention ranged from 4.2 to 7.1[16,24-32]. In Kim and Cho's study, the mean pre-intervention VAS score decreased from 8.35 to 4.16 during the 1st month of the implementation and to 3.25 during the 2nd month [15]. In Vallai et al.'s study, the intensity level of the pain which was 4.24 before the intervention decreased to 1.95 during the first menstrual cycle and to 1.28 during the second menstrual cycle[16]. As was done in this study, Wu implemented reflexology and foot massage to treat dysmenorrhea and reported that mean scores in both groups decreased the same and that there were no statistical differences between the groups[23]. These results indicate that both reflexology and foot massage are effective methods in reducing the symptoms of dysmenorrhea.

While the non-specific foot massage was implemented, in order not to send the message to the corresponding organ, warming movements which are part of the reflexology massage were not performed. However, although only the eyes, ears and outside of the foot were massaged in the control group, their pain scores decreased as did those of the reflexology group. Relaxation experienced in the placebo group may have been due to the massage and touch or due to the close communication established with and attention paid to the students.

The pain and discomfort felt during the premenstrual period is a part of an individual's description of pain. In the present study, the pain descriptions according to the Verbal Category Scale were also evaluated. During the before the intervention period, approximately half of the students in the RG and two-thirds of the students in the PG described their pain level as very severe (Table 3). In Eryılmaz et al.'s and Gilany et al.'s studies, approximately half of the participants described their pain as severe[33,34]. In another study, 41 percent of the participants described their pain as very severe[35]. Similar to other studies, in the present study, the majority of both groups described their pre-intervention pain as severe or very severe. While more than half of the students in both groups perceived their pain as very severe at the beginning of the study, during the first cycle, only one-fifth of the students in both groups perceived their pain as very severe. In other words, after the reflexology and foot massage, the rate of those who perceived their pain as very severe / unbearable was 3.5-4 times less. In addition, the increase observed in the symptoms of dysmenorrhea during the control month when no massage was implemented confirms the effects of reflexology and foot massage on pain. After the intervention, about half of the students in both groups said that the pain they experienced at the onset of the pain was severe. Some of the students said that they experienced no pain after the intervention (Table 3). This result indicates that massage application changed the students' perception of pain, and thus they felt less pain. Foot massage reduced pain as did reflexology massage. Communication established with students during and after the sessions affected dysmenorrhea. Massage applied on feet even without applying pressure to the reflexology points provided relief and thus changed the students' perception of pain due to touches on the feet. Although there are no studies conducted on the relationship between therapeutic touch and dysmenorrhea, there are some studies indicating that therapeutic touch reduces pain [36-38]. One of the limitations of the study is that time was not allocated to the sessions appropriately, because the students' school program was very intensive and they had to leave the city very often when the study was conducted.

In this present study, reflexology and foot massage were effective in dysmenorrhea In order to determine the effects of reflexology and foot massage on dysmenorrhea in detail, it is recommended that reflexology and foot massage should be applied during different phases of the menstrual cycle under laboratory conditions

Yazar Katkıları: Çalışma konsepti/Tasarımı: FAY, MB; Veri toplama: FAY; Veri analizi ve yorumlama: FAY, MB; Yazı taslağı: FAY; İçeriğin eleştirel incelenmesi: FAY, MB; Son onay ve sorumluluk: FAY, MB; Teknik ve malzeme desteği: FAY; Süpervizyon: FAY, MB; Fon sağlama (mevcut ise): yok.
Bilgilendirilmiş Onam: Katılımcılardan yazılı onam alınmıştır.
Hakem Değerlendirmesi: Dış bağımsız.
Çıkar Çatışması: Yazarlar çıkar çatışması beyan etmemişlerdir.
Finansal Destek: Yazarlar finansal destek beyan etmemişlerdir.

Author Contributions: Concept/Design : FAY, MB; Data acquisition: FAY; Data analysis and interpretation: FAY, MB; Drafting manuscript: FAY; Critical revision of manuscript: FAY, MB; Final approval and accountability: FAY, MB; Technical or material support: FAY; Supervision: FAY, MB; Securing funding (if available): n/a.
Informed Consent: Written consent was obtained from the participants.
Peer-review: Externally peer-reviewed.
Conflict of Interest: Authors declared no conflict of interest.
Financial Disclosure: Authors declared no financial support

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