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Original Article

Comparison of maximum pain intensity and duration of primary dysmenorrhea after acupressure on third liver and placebo points: A double-blind randomized controlled clinical trial

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ARTICLE INFO	ABSTRACT	
Received 25 November 2013 Revised 1 December 2013 Accepted 28 December 2013 Published 25 December 2014	Background & Aim: Primary Dysmenorrhea (PD) is the most common genital disease among adults which can disrupt daily activities and reduce quality of life. Acupressure was recommended for relief of PD and the aim of this study was to compare the maximum pain intensity (MPI) and duration of PD after acupressure on third liver (LIV3) and placebo points.	
Available online at: http://npt.tums.ac.ir	Methods & Materials: Students who were suffering from PD were studied for three menstrual cycles between March and June 2012. In the first cycle, intensity and duration of dysmenorrhea (DPD) were assessed and students with pain score≥4 according to visual analogue scale for MPI were selected. Randomized block allocation was performed based	
Key words: acupressure, dysmenorrhea, third liver, pain, duration,	on pain intensity with 1:1 allocation ratio. Students, data analyzer and allocation were blind. Students applied acupressure themselves, on LIV3 or placebo points in the second and third cycles, only on first day of menstrual cycles in the beginning of bleeding. Acupressure was performed 4 times intermittently, (2 minutes pressure followed by 2 minutes rest, twice on each leg and 16 minutes in total). Chi-square, Mann –Whitney, Wilcoxon, Sign test and ordinal regression analysis were used.	
intensity	 Results: In LIV3 group 27 and in control group 32 students were analyzed. MPI in each group decreased after intervention but decrease in DPD was not significant. There were not significant differences between groups based on ordinal regression test for MPI and DPD (p>0.05). Conclusion: Pressure at LIV3 point decreased MPI but was not significantly effective in reducing DPD. Further studies in more menstrual cycles and other techniques are recommended. 	
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Introduction

Primary Dysmenorrhea (PD) is uterine muscle spasm that occurs during menstruation

* Corresponding Author: Neda Mirbagher-Ajorpaz, Department of Nursing, Kashan University of Medical Sciences, Kashan, Iran. Email: mirbagher_n@kaums.ac.ir days (1). It is the most common genital disease among adults (2). Prevalence of dysmenorrhea is reported up to 97% and 10% of patients are absent from their job due to dysmenorrhea each month (3). Several factors affect PD such as: age at menarche, weight, menstrual intervals, duration of bleeding and family history of

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dysmenorrhea (4-11). Nowadays PD can be treated by analgesics, oral contraceptive pills, and non-steroidal anti-inflammatory drugs (NSAID). These treatments have many adverse side effects. One study reported 42389 adverse drug reactions during 2002-2006 in France for NSAIDs including coetaneous, gastrointestinal, hepatic, renal and rarely, cardiovascular events (12). Thus, there is a tendency to find relief of PD without side effects. Another treatment in traditional Chinese Medicine (TCM) for PD is acupressure. Acupressure is stimulation of acupoints by means of pressure, usually using fingers or thumb. According to TCM there are 14 meridians for flow of energy in the body that cross vital organs. Energy imbalance can cause symptoms that based on modern medicine its physiological function is unknown. Acupressure balances the flow of energy (chi) in the body and is used to treat PD. Adjustment the flow of energy within the body's organs such as the spleen, liver and kidney can be useful in treatment of dysmenorrhea (3, 13-18). Spleen sixth (SP6) acupressure point is commonly used for reproductive problems in women, such as menstrual symptoms (19) and pain relief in labor (20). There are reports of reduced pain (2, 19-21) and duration of dysmenorrhea by pressure at SP6 point (22) and contradictory report of no difference in pain duration before and after pressure at this point (23). Also third liver point (LIV3) helps to regulate the flow of energy and liver function. Bazarganipour et al. (2010) study showed that pressure on LIV3 is effective for reducing severity and duration of PD (3). This is the only study that we found about LIV3 acupoint and dysmenorrhea. Therefore studies about effectiveness of acupressure on PD were insufficient, suggesting further studies on this issue (3,15,20).

In view of the adverse effects of existing treatments and simplicity of acupressure in the treatment of PD and general lack of studies in this area, especially in LIV3 point, the aim of this study was to compare the maximum pain intensity and duration of PD after acupressure at LIV3 and placebo points.

Methods

This is a clinical trial that was performed in treatment and placebo groups according to a design registered in Iranian Registry of Clinical Trials (IRCT). Its registration ID is: IRCT201201308869N1.

Students living at dormitories of Kashan University of Medical Sciences in Iran who were suffering from PD were studied for three menstrual cycles between March and June 2012. Inclusion criteria were: living at the dormitory, being single, regularity of menses, start of pain with the onset of menstrual bleeding, duration of bleeding between 3-8 days and menstrual intervals of 21-35 days, pain with a score of at least 4 of 10 according to the visual analogue scale (VAS) criteria for pain intensity in most menstrual cycles, lack of pain throughout the all times of menstrual cycle or bleeding, lack of anemia or high blood pressure, no psychiatric disorders especially depression (more than 19 point according to the Beck-21 criteria for depression) (3), no secondary dysmenorrhea, no severe psychological stress in the past 6 months (e.g., family death, surgery, marriage, separation of parents), absence of any problems in the pressure point such as fractures, ulcers, varicose veins, skin disease or inflammation. Exclusion criteria were: any known disease of genital tract, systemic disorders, use of oral contraceptive NSAIDs, analgesics, prostaglandins pills, synthesis inhibitors for 4 hours before till 4 hours after applying pressure, use of heat, unwillingness to cooperate until the end of the study (3 cycles).

In the Kashefi et al. study (17), the average pain intensity in the second hour after intervention in the treatment and control groups were 4.55 ± 1.60 and 6.34 ± 1.57 . Therefore, according to the following formula: $N = [Z (1-\alpha)]$ $(2) + Z (1-\beta) = 2 (S12+S22) / (X1-X2)^2$ with 90% power and 95% confidence interval minimum sample size of 23 patients per group was needed. Regarding to inclusion and exclusion criteria and with regard to 30% possible loss of the samples, 500 students who were living in the residence hall were invited for participation. The only observer was third author of this article who was midwifery student and performed sampling. She has been in constant contact with the students face to face. Also she controlled proper technical of pressure that was applied by students. Initially, 104 students fulfilled inclusion criteria. They received explanation about acupressure and informed consents were obtained. Participants completed the Beck-21 depression scale to exclude samples who have depression score > 19. They received a questionnaire containing

demographic and menstrual cycle information. Intensity and duration of pain was measured on the first day of the first cycle without intervention using VAS for pain intensity. At this time 67 samples with a pain score ≥ 4 remained to participate in the study.

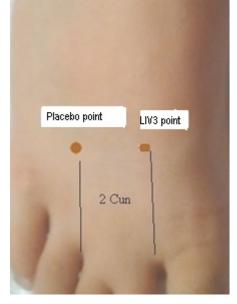
Subjects were divided into two parallel groups, including group a (placebo point) and group b (LIV3 point) using a randomized block allocation (allocation ratio 1:1) based on pain intensity.

Group division was determined by someone who was unaware of the experimental groups using a random number that was conducted by demographer. The research unit and data analyzer were not aware of intervention and control groups.

First researcher received training in acupressure from the TCM professor. LIV3 point is located 2 Cun (width of three fingers) above the distance between the first and second metatarsal bones and the placebo point was located 2 Cun above the distance between the third and fourth fingers (Figure 1) (14).

The subjects were instructed to find the exact location of pressure points and apply the pressure with correct techniques. Acuhealth device was used to ensure the accuracy of pressure points and Force Gauge was used for unification of pressure. Firstly, pressure was applied by researcher on pressure points and continued until research unit announce De chi (i.e. feeling of tingling, heat, cold, creep). At this time the pressure that was indicated on the gauge's screen was recorded. Then the subject

Figure 1: LIV3 and placebo points.



was asked to apply the same pressure and pay attention to her nail color change. After then she made so pressure till same color change occurred. Students applied acupressure themselves, on LIV3 or placebo points in the second and third cycles, only on first day of menstrual cycles in the beginning of bleeding. Acupressure was performed 4 times intermittently, (2 minutes pressure followed by 2 minutes rest twice on each leg and 16 minutes in total) in the clockwise rotation. Each time the pressure would stop with the sense of De chi, otherwise continued for 2 minutes and was resumed after 2 minutes on the other foot. The alternation of pressure and rest continued for 16 minutes. The pain was measured immediately and 0.5, 1, 2, 3 and 4 hours after the start of the bleeding according to the VAS criteria for pain intensity. After this, students were allowed to use painkiller.

Primary outcome of this study was pain intensity and the secondary outcome was pain duration.

Force Gauge device determine the pressure applied by the researcher finger. This device is made in Taiwan and has international standard of European Union and valid certificate of calibration ISO 9001 (13). Australian acuhealth professional 900 devices were used. It produces different sound in order to find the correct acupressure point. This device is approved by American Food and Drug Administration and approved by Iranian Ministry of Health and Medical Education (13). This device has been used in several studies and its reliability has been confirmed previously (3, 13). A made in Germany digital glass scale (GS46) with 100 grams accuracy was used to measure the weight and a single non-elastic tape was used to measure the height.

Beck-21 Depression Inventory for adults has 21 groups of questions that each group will receive a score of zero to 3, and a total of 63 points. Overall rating scale of <10 indicates no or minimal depression, 10 to 18 indicates mild to moderate depression, 19 to 29 indicates moderate to severe depression, and 30 to 63 indicate severe depression (24). The validity of this inventory has been approved previously (24,25) and its reliability was confirmed in this study (Cronbach's alpha was 0.887). VAS pain scale questionnaire is a ruler that research unit marked it upon the pain. Distance from the beginning of the ruler to marked point in centimeter would be measured pain score (1, 2).

VAS is a reliable and valid tool for subjective experiences including pain (2). Also the content validity of the questionnaire was determined by a panel of 10 experts including MS in Midwifery, MS in Nursing and obstetricians.

A female student was in constant contact with students and controlled the proper technique of pressure. Students received enough information about the research and also about the dysmenorrhea and possible effect of acupressure on it. They were informed that they were free to participate in the research and their informed consents were obtained.

Data were analyzed using SPSS v.11 (SPSS Inc. II Chicago, USA). Confounding variables including history of dysmenorrhea in first degree relatives, age at menarche, menstrual duration and body mass index (BMI) were frequently matched in groups. Data were reported with a mean (±SD) for quantitative, frequency (%) for qualitative and median Inter Quartile Range (IQR) for ordinal variables. Sign test was used to compare maximum pain intensity and Wilcoxon test to compare pain

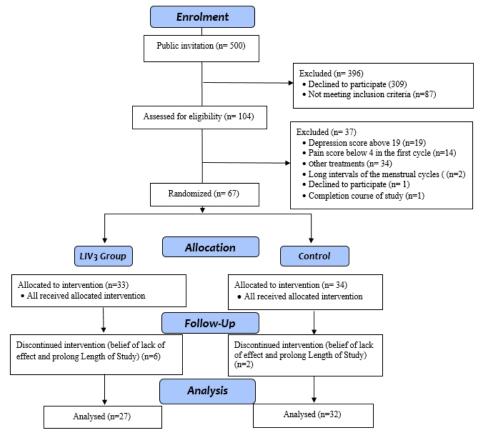
Figure 2: Flow Diagram.

duration before and after acupressure in each group. Mann-Whitney test was used to compare pain duration between groups in first cycle. To compare pain duration between groups after intervention ordinal regression, with adjustment for the baseline values in first cycle, was used. P<0.05 was considered statistically significant.

Results

Five hundred students who were lived at the dormitory were invited to participate in the study. Finally 32 students in control group and 27 in LIV3 group remained for analyses with regard to inclusion and exclusion criteria and pain score \geq 4. Figure 2 shows the process of loss.

Students studied at 8 different fields of medical sciences. Mean (\pm SD) age and BMI of students were 21.750 \pm 2.797 years and 20.463 \pm 3.161 kg/m2 respectively. There were no statistically significant differences between two groups for these characteristics (p>0.05). Mean (\pm SD) age at menarche, bleeding duration



	Groups		
Cycles	Control (n=32)	LIV3 (n=27)	
	median (IQR)	median (IQR)	
1	7.00 (4.00)	8.00 (4.00-)	
2	6.00 (4.75)	5.00 (5.00)	
3	4.50 (3.00)	5.00 (5.00)	
P (Cycles 1-2)	0.021	0.064	
P (Cycles 1-3)	0.001	0.012	
P (Cycles 2-3)	0.248	0.383	

Table 1: Comparison of maximum pain intensity before and after treatment within each group

Sign test

 Table 2: Comparison of pain duration before and after treatment within each group

	Groups	
Cycles	Control(n=32)	LIV3 (n=27)
	median (IQR)	median (IQR)
	(hours)	(hours)
1	7.00 (7.38)	6.00 (26.00)
2	5.00 (21.00)	6.00 (21.00)
3	4.50 (16.00)	4.00 (9.00)
P (Cycles 1-2)	0.599	0.391
P (Cycles 1-3)	0.081	0.052
P (Cycles 2-3)	0.334	0.322

Wilcoxon test

and menstrual intervals were 13.293 ± 1.130 , 26.178 ± 3.692 and 6.464 ± 1.318 respectively. There were no statistically significant differences between two groups for these characteristics (p>0.05). History of PD in first degree relatives were 12 (66.70%) in control group and 5 (45.50%) in LIV3 group. This difference was not statistically significant (p>0.05).

Comparison of maximum pain intensity before and after intervention within groups showed significant differences between first and third cycles in both groups (p<0.05) (Table 1).

Comparison of pain duration before and after intervention within groups showed no significant difference between first and third cycles (p>0.05) (Table 2).

There were not significant differences for maximum pain intensity between groups in three cycles. Also table 3 shows that there are not significant differences in pain duration between groups in three cycles.

No adverse effects of acupressure were reported by participants.

Discussion

In this study, participants had the age range

similar to other related studies (3,16,17,19,20).

Participants in this study had similar BMI as a confounding factor in interventional groups. There are conflicting reports in this area. Thin people have a higher risk of PD (4, 8) and PD associate with BMI (5,10). Contradictory it was said that the extra weight had an important effect on uterine cramps and duration of PD during the menstruation (11). However, this variable was identical in 2 groups of this study.

In the present study, mean (\pm SD) age at menarche, menstrual intervals, and duration of bleeding were similar in interventional groups. Studies showed that age at menarche (4-6), menstrual intervals (7) and bleeding duration (5) affect PD.

In this study, family history of PD has no significant difference between groups (p>0.05). Other studies showed that dysmenorrhea is more common in people with family history of PD (8,9).

In this study there was no significant difference in pain duration at the first cycle between groups. This indicates that both groups had similar pain before pressure. Similarly no differences were noted in other studies (17, 19). This study showed significant reduction in maximum pain intensity of dysmenorrhea in both groups. The only published study that we found about effectiveness of pressure at LIV3 point on intensity of dysmenorrhea reported reduced pain after acupressure at LIV3 point (3). Pressure at Sp6 point that is another acupoint was reported to reduce the pain of dysmenorrhea in previous studies (17, 21).

In this study pressure at placebo point reduced pain intensity in second and third cycles, whereas in LIV3 group, reduction appeared at third cycle. This placebo point was undefined in extra acupoints previously and its efficacy was notable. Formerly pain reduction in control group was seen in some studies (3, 17), but not all of them (20) and not more than treatment group.

There is a reduction in duration of PD in both groups that was close to statistically significant level. A study was within in a longer period, may yield statistically significant reduction. Bazarganipour et al showed statistically significant reduction in duration of pain after pressure on LIV3 point (3). But our study had different approach to pressure. In their study, pressure was carried out 3-7 days prior to menstruation for 20 minutes per day only on right foot. In our study, the pressure was

performed at the start of bleeding for less time (16 minutes) on both feet. Another difference was that they applied acupressure during three cycles, whereas we performed in two cycles. Acupressure may be more effective in the long term because in the Lin et al. study it was suggested that there is a long-lasting amelioration on dysmenorrhea (18). As well there are some reports about SP6 point in this regard. Bostani et al reported reduced duration of dysmenorrhea by pressure at SP6 point (22), and contradictory report of no difference in pain duration before and after pressure at this point was reported by Suhrabi et al (23).

Current study showed no statistically significant difference in pain duration between groups in the third cycle (p>0.05). However, in Bazarganipour et al (2010) study, the differences between groups were created progressively over 4 cycles (3) maybe due to a longer period pressure. The pressure may require a longer time to be effective. Also she selected people who had clinical symptoms of liver channel involvement.

Conclusions

Acupressure at LIV3 was effective to reduce intensity of dysmenorrhea but there was no significant reduction in duration of dysmenorrhea using a technique that was applied in this study. Better judgment will be possible with increasing number of interventional cycles. On the other hand reduction in pain intensity after pressure at placebo point should be considered. This point was undefined in extra points previously. Therefore further studies are recommended on this point.

Limitations: Samples are exposed to many environmental changes in long-term studies. These changes can affect PD and uncontrollable by the researcher. Also the long term of study and frequency of measurements caused loss of samples and reduction of participant's number.

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Conflicts of interest

There is no conflict of interest.

References

- Aghamiri Z, Vigeh M, Latifnezhead R, Nabavi S. Study of effect of acupressure methods on pain in primary dysmenorrhea. The Journal of Faculty of Nursing & Midwifery 2005;11(3-4):19-28.
- 2. Chen HM, Chen CH. Effects of acupressure at the Sanyinjiao point on primary dysmenorrhoea. J Adv Nurs2004;48(4):380-7.
- 3. Bazarganipour F, Ahmari Tehran H, Heshmat R, Asghari JaafarAbadi M, Lamyian M. Evaluation of the effect of liv3 acupressure on severity and duration of primary dysmenorrhea. Knowledge & Health. 2010; 5(1):27-35.
- 4. Hirata M, Kumabe K, Inoue Y. Relationship between the frequency of menstrual pain and bodyweight in female adolescents. Nihon Koshu Eisei Zasshi. 2002-Jun;49(6):516-24.
- Hossain MG, Sabiruzzaman M, Islam S, Hisyam RZ, Lestrel PE, Kamarul T. Influence of anthropometric measures and sociodemographic factors on menstrual pain and irregular menstrual cycles among university students in Bangladesh. Anthropol Sci. 2011 Dec;119(3):239-46.
- Yamamoto K, Okazaki A, Sakamoto Y, Funatsu M. The relationship between premenstrual symptoms, menstrual pain, irregular menstrual cycles, and psychosocial stress among Japanese college students. J Physiol Anthropol. 2009;28(3):129-36.
- Iliyasu Z, Galadanci HS, Abubakar IS, Ismail AO, Aliyu MH. Menstrual patterns and gynecologic morbidity among university students in Kano, Nigeria. J Pediatr Adolesc Gynecol. [Article]. 2012 Dec;25(6):401-6.
- Ozerdogan N, Sayiner D, Ayranci U, Unsal A, Giray S. Prevalence and predictors of dysmenorrhea among students at a university in Turkey. Int J Gynaecol Obstet. [Article]. 2009 Oct;107(1):39-43.
- Chuamoor K, Kaewmanee K, Tanmahasamut P. Dysmenorrhea among Siriraj nurses; Prevalence, Quality of Life, and Knowledge of Management. Journal of the Medical Association of Thailand. 2012 Aug;95(8):983-91.
- 10. Nohara M, Momoeda M, Kubota T, Nakabayashi M. Menstrual cycle and menstrual pain problems and related risk factors among japanese female workers. Ind Health.. 2011 Mar;49(2):228-34.
- 11. Harlow SD, Park M. A longitudinal study of risk factors for the occurrence, duration and

severity of menstrual cramps in a cohort of college women (vol 103, pg 1134, 1996). Br J Obstet Gynaecol. 1997 Mar;104(3):386-.

- 12. Lapeyre-Mestre M, Grolleau S, Montastruc JL, Assoc Francaise Ctr R. Adverse drug reactions associated with the use of NSAIDs: a case/noncase analysis of spontaneous reports from the French pharmacovigilance database. 2002-2006. Fundam Clin Pharmacol. 2011 Apr;27(2):223-30 [Abstract].
- 13. Bazarganipour F, Lamyian M, Heshmat R. The effect of applying pressure to the third liver point on the symptoms of involved liver channel in girls with primary dysmenorrhea: A randomized clinical trial. Arak Medical University Journal 2010;13(2):17-25.
- 14. Bazarganipour F, Lamyian M, Heshmat R, Abadi MA, Taghavi A. A randomized clinical trial of the efficacy of applying a simple acupressure protocol to the Taichong point in relieving dysmenorrhea. Int J Gynaecol Obstet 2010 Nov;111(2):105-9.
- Cho SH, Hwang EW. Acupressure for primary dysmenorrhoea: A systematic review. Complement Ther Med 2009;18(1):49-56.
- 16. Gharloghi S, Torkzahrani S, Akbarzadeh AR, Heshmat R. The effects of acupressure on severity of primary dysmenorrhea. Patient Prefer Adherence 2012;6:137-42.
- 17. Kashefi F, Ziyadlou S, Khajehei M, Ashraf AR, Fadaee AR, Jafari P. Effect of acupressure at the Sanyinjiao point on primary dysmenorrhea: a randomized controlled trial. Complement Ther Clin Pract 2010-Nov;16(4):198-202.
- 18. Lin JA, Wong CS, Lee MS, Ko SC, Chan SM, Chen JJ, et al. Successful treatment of primary dysmenorrhea by collateral meridian

acupressure therapy. J Manipulative Physiol Ther2010 Jan;33(1):70-5.

- 19. Charandabi MA, Sakineh., Nashtaei MS, Kamali S, Majlesi R. The effect of acupressure at the Sanyinjiao point (SP6) on primary dysmenorrhea in students resident in dormitories of Tabriz. Iran J Nurs Midwifery Res 2011;16(4):309-17.
- 20. Mirbagher-Ajorpaz N, Adib-Hajbaghery M, Mosaebi F. The effects of acupressure on primary dysmenorrhea: a randomized controlled trial. Complement Ther Clin Pract 2010 Feb;17(1):33-6.
- 21. Chen HM, Chen CH. Effects of acupressure on menstrual distress in adolescent girls: a comparison between Hegu-Sanyinjiao matched Points and Hegu, Zusanli single point. Journal of Clinical Nursing 2010;19(7-8):998-1007.
- 22. Bostani Khalesi Z, Abadin Zadeh M, Safari A. Compared the effects of acupressure and vitamin E in the primary dysmenorrhea Saninjiao. Armaghane-danesh 2009;14(3):36-43.
- 23. Suhrabi Z TM, Javadifar N. Comparison of Pressure Effect on Sanyinjiao point with that of Ibuprofen on primary dysmenorrhea. Journal of Ilam University of Medical Sciences 2006;14(2):30-5.
- 24. Beck A, I., Steer R, A., Carbin M. Psychometric properties of the Beck depression inventory: twenty-five years of evaluation. Clinical Psychology Review1988;8(1):77-100.
- 25. Kaviani H, Ahmadi Abhari S, Nazari H, Hormozi K. Prevalence of depressive disorders in Tehran resident population, 2000. The Journal of Tehran Faculty of Medicine 2002;60(5):399-3.