

Comparison of Mean Pain Score with Vitamin E in Combination with Mefenamic Acid Versus Mefenamic Acid Alone for Management of Primary Dysmenorrhea

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ABSTRACT

Background: Primary dysmenorrhea is a usual and most common gynecological complaint, mainly in teenagers, that is described as a cramping pain in the lower abdomen during menstruation in the absence of any pelvic pathology.

Aim: To compare the mean pain score with vitamin E supplementation in combination with mefenamic acid versus mefenamic acid alone for the management of primary dysmenorrhea.

Methods: This randomized control trial was conducted in Gynae Unit II, Services Hospital, Lahore. It was done for six months from July to December 2016. The technique used was non-probability, consecutive sampling technique conducted after taking Informed consent from all the patients. The data was collected in the forms of two groups. Data analysis was done on SPSS version 16.

Results: In our study the mean age of the female patients was 14.96 ± 2.05 years. The mean value of BMI of the group A patients was 20.51 ± 1.34 kg/m² and its mean value in group B patients was 20.58 ± 1.35 kg/m². Statistically highly significant difference was found between the study groups with the pain score of the patients i.e., p-value=0.000.

Conclusion: The combination of Mefenamic acid with vitamin E is significantly more effective and showed reduced pain score compared to Mefenamic acid alone for management of primary dysmenorrhea.

Keywords: Dysmenorrhea, Mefenamic, Combination, Primary, Vitamin E

INTRODUCTION

Primary dysmenorrhea is a usual gynecological complaint, particularly in teenagers, that is described as a cramping pain in the lower abdomen during menstruation. The incidence of primary dysmenorrhea ranges from 20 to 90% in menstruating females¹.

Pain is due to ischemia, induced by PGE₂, caused by uterine contractions, narrowing of cervix and increased release of vasopressin². Non-steroidal anti-inflammatory drugs (NSAIDs) and oral contraceptive pills, by reducing uterine contractions, are the common treatment options for dysmenorrhea.

Due to the likely side effects of medications, many clients are now trying alternate customary treatments. There is evidence approving that the dietary intake and metabolism may play an important role in the origin and treatment of menstrual disorders³.

Vitamin E is an antioxidant agent and gives protection to body tissues from damage caused by free radicals. Vitamin E is used for treating vitamin E deficiency, as well as it is essential for preventing other problems in the body⁴.

One study conducted on 100 girls (50 girls in each group) reported that mean pain score after management with vitamin E was 3.5 ± 1.25 while with placebo, mean pain score was 4.3 ± 1.13 after 2 months. This difference was statistically significant ($p=0.02$)⁵.

Later on, results of another randomized trial conducted on 278 girls (139 girls in each group) also agreed with results of previous study and reported that mean pain score after management with vitamin E was 3 ± 0.625 while with placebo, mean pain score was 5 ± 0.75 after 2 months. This difference was statistically significant ($p=0.000$)⁶.

Rationale of this study is to compare the mean pain score with vitamin E supplementation versus placebo in combination with mefenamic acid for management of primary dysmenorrhea. Literature has reported that vitamin E is beneficial in suppressing dysmenorrhea in teenage girls. But not much work has been done regarding the effect of vitamin E on dysmenorrhea.

Moreover, no local evidence was found on the basis of which we can implement the use of vitamin E in girls with severe menstrual pain. Through this study we want to assess the effect of vitamin E to reduce pain, so that in future we can implement the results of this study and can prescribe vitamin E in girls instead of medicines, which may have side effects. So this study will also help to attain local magnitude as well. We will also take large sample size to gain more accurate results, which will be applicable in local population in future. This will also improve local guidelines as well as improve our practice.

The objective of the study was to compare the mean pain score with vitamin E supplementation in combination with mefenamic acid versus mefenamic acid alone for management of primary dysmenorrhea, is the objective of this study.

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OPERATIONAL DEFINITIONS

Primary dysmenorrhea: It was labeled as cramping pain ≥ 4 (on VAS) in the lower abdomen arising at the onset of menstruation in the absence of any recognizable pelvic pathology (on clinical examination and USG) for adenomyosis, fibroid, endometriosis.

Pain score: It was measured on visual analogue scale (incorporated in proforma) after 2 months of initial management, where 0=no pain, 10=worst possible pain.

MATERIALS & METHODS

This Randomized Controlled Trial was done in Gynae Unit II, Department of Obstetrics & Gynecology, Services Hospital, Lahore for six months from July to December 2016 on 300 cases; 150 cases in each group. The sample size was calculated with 95% confidence level, 80% power of test and taking magnitude of mean pain score i.e. 3.5 ± 1.25 with vitamin E and 4.3 ± 1.13 with placebo in combination with mefenamic acid for management of primary dysmenorrhea. Non-Probability, Consecutive sampling was used. Inclusion criteria were unmarried girls of age 12-18 years presenting with primary dysmenorrhea (as per operational definition) with baseline pain score ≥ 4 on VAS. Patients with some pathology inside uterus or ovaries like PCO (LH/FSH ration >1) were excluded.

After taking approval from ethical committee of the hospital, 300 girls satisfying the selection criteria were included in the study from outdoor of Obstetrics & Gynecology Department, Services Hospital, Lahore. Informed consent was taken. Demographic data (name, age, BMI and contact) was noted. Then girls were randomly divided in two groups. In group E, girls were prescribed vitamin E along with mefenamic acid (Ponstan forte) for 5 days at the beginning of menstruation for 2 months. In group P, girls were prescribed mefenamic acid only for 2 months. Then girls were asked to report about pain status after 2 months (2 menstrual cycles) on OPD. After 2 months, pain was assessed again. All this information was filled in the proforma.

The data was analyzed through SPSS version 16. Mean and SD was calculated for quantitative variables like age, and pain after 2 months. Frequency and percentage was given for qualitative variables like BMI status. Both groups were compared by using independent sample t-test for mean pain score, p-value <0.05 as significant. Age, educational status and BMI of patients were effect modifiers and were controlled through stratification. Post-stratification, independent sample t-test was applied with p-value ≤ 0.05 as significant.

RESULTS

In this study 300 girls were enrolled. The mean age of the patients was 14.96 ± 2.05 years with minimum and maximum ages of 12 & 18 years respectively. The mean age of the group A patients was 15.04 ± 1.94 years and its mean value in group B patients was 14.87 ± 2.15 years.

The mean height of the group A patients was 1.58 ± 0.041 meter and its mean value in group B patients was 1.57 ± 0.041 meters. The mean weight of the group A patients was 51.58 ± 2.85 kg and its mean weight in group B patients was 51.27 ± 2.55 kg.

The results showed that the mean BMI of the group A patients was 20.51 ± 1.34 kg/m² and its mean value in group B patients was 20.58 ± 1.35 kg/m².

The illiterate patients were 80(26.67%), the patients with middle education status were 129(43%), the patients with matric-FA were 72(24%) and the patients with BA and above were 19(6.33%).

The mean value of the pain score of the patients was 3.02 ± 1.32 with minimum and maximum score values of 1 & 5 respectively. The mean pain score value of group A patients was 1.98 ± 0.815 and group B patients was 4.06 ± 0.813 . Statistically highly significant difference was found between the study groups with the pain score of the patients i.e., p-value=0.000.

The results of study showed that in patients with age between 12-15 years, the mean value of pain score in group A was 1.94 ± 0.80 and its mean value in group B was 4.10 ± 0.81 . Similarly in patients with age between 16-18 years, the mean pain score in group A was 2.03 ± 0.83 and its mean value in group B was 4.00 ± 0.82 . Statistically very significant difference was found between the study groups with pain score stratified by age. i. e p-value=0.000, 0.000 respectively.

The study results showed that in patients underweight BMI, the mean pain score value was 1.99 ± 0.81 in group A and 4.07 ± 0.82 in group B. Similarly in patients with normal BMI, the mean pain score in group A was 2.00 ± 1.00 and its mean value in group B was 4.00 ± 0.57 . Statistically highly significant difference was found between the study groups with pain score stratified by BMI i.e., p-value=0.000, 0.000 respectively.

By stratifying the educational status, difference observed between the study groups with pain score i.e., p-value=0.000, 0.000, 0.000 & 0.000 respectively was highly significant.

DISCUSSION

This randomized control trial was conducted in Unit II Department of Obstetrics & Gynecology, Services Hospital, Lahore to compare the mean pain score with vitamin E supplementation in combination with mefenamic acid versus mefenamic acid alone for management of primary dysmenorrhea.

Dysmenorrhea is an extremely common and sometimes incapacitating condition for reproductive age women. A multidisciplinary approach, using a combination of lifestyle, drugs, and allied health services should be used to constraint the influence of this condition on daily life activities⁷⁻⁹.

40% of adult women experience dysmenorrhea and more than 10% report severe restriction of social activity for one to three days per cycle and socio-economic load of such limitations.

According to our study results, the combination of Mefenamic acid plus vitamin E (Group A) showed significantly effective results as compared to Mefenamic acid (Group B) alone in management of primary dysmenorrhea. The mean pain score value of group A patients was 1.98 ± 0.815 and its mean value in group B patients was 4.06 ± 0.813 i.e., p-value=0.000. There was also significant relation noted between the study groups

and mean pain score when data was stratified by age, BMI and education.

Some of the studies as discussed below show the results in favour of our study as a study by laghmai et al¹¹ reported that the mean of maximum pain difference before and after treatment in the group receiving mefenamic acid and vitamin E was 48.5±17.5, but in the group taking mefenamic acid and placebo, this scale was 25.9±21, and the difference was significant (P < 0.001).

One study conducted on 100 girls (50 girls in each group) reported that mean pain score after management with vitamin E was 3.5±1.25 while with placebo, mean pain score was 4.3±1.13 after 2 months. This difference was statistically significant (p=0.02)⁵.

Another study concluded that the duration and severity of pain of primary dysmenorrhea was significantly reduced with vitamin E taken at a dose of 200 mg daily for five days at the start of menstruation. They also noted reduction in menstrual blood loss, without any significant side effects⁷.

Another randomized trial conducted on 278 girls (139 girls in each group) also agreed with results of previous study and reported that mean pain score after management with vitamin E was 3±0.625 while with placebo, mean pain score was 5±0.75 after 2 months. This difference was statistically significant (p=0.000)⁵.

The study results of Minoo Yaghmaei et al¹² confirmed that the pain relief in the group who received Mefenamic acid and vitamin E combination was better than the group who received Mefenamic acid and placebo (p<0.001).

Another study conducted in 2001 described that both placebo and vitamin E were efficient in allaying symptoms due to primary dysmenorrhoea, but the results of vitamin E were more marked. These differences were sustained in the second month of treatment.¹³

One study by Masoomeh Nasehi et al¹⁴ resulted that the mean of peak pain intensity in the first, second, third, sixth, and forty-eight hours in the group that had used fennel extract/vitamin E combination was less than the group that had used ibuprofen, and statistical differences were seen between the two groups in the first and second hours; fennel extract/vitamin E combination was more effective than ibuprofen in the first hour (P < 0.03) and second hour (P < 0.04).

CONCLUSION

It has been proved in our study that Mefenamic acid and vitamin E combination is significantly more effective and showed reduced pain score compared to Mefenamic acid alone for management of primary dysmenorrhea.

REFERENCES

1. Liu C-F. Acupuncture or Acupressure at the Sanyinjiao (SP6) Acupoint for the Treatment of Primary Dysmenorrhea: A Meta-Analysis. *Evid Based Complement Alternat Med*. 2013;2013:Article ID 493038.

2. Grandi G, Ferrari S, Xholli A, Canoletta M, Palma F, Romani C, et al. Prevalence of menstrual pain in young women: what is dysmenorrhea? *J Pain Res*. 2012;5:169.
3. Direkvand-Moghadam A, Khosravi A. The impact of a novel herbal Shirazi Thymus Vulgaris on primary dysmenorrhea in comparison to the classical chemical Ibuprofen. *J Res Med Sci*. 2012;17(7):668–70.
4. WebMD. Vitamin E. 2009 [cited 2014]; Available from: <http://www.webmd.com/vitamins-supplements/ingredientmono-954-vitamin%20E.aspx?activeIngredientId=954&activeIngredientName=vitamin%20E>.
5. Ziaei S, Faghihzadeh S, Sohrabvand F, Lamyian M, Emamgholy T. A randomised placebo-controlled trial to determine the effect of vitamin E in treatment of primary dysmenorrhoea. *Br J Obstet Gynaecol*. 2001;108(11):1181-3.
6. Ziaei S, Zakeri M, Kazemnejad A. A randomised controlled trial of vitamin E in the treatment of primary dysmenorrhoea. *Br J Obstet Gynaecol*. 2005;112(4):466-9.
7. Ziaei S, Zakeri M, Kazemnejad A. A randomised controlled trial of vitamin E in the treatment of primary dysmenorrhoea. *BJOG: An International Journal of Obstetrics & Gynaecology*. 2005;112(4):466-9.
8. Wu D, Mura C, Beharka AA, Han SN, Paulson KE, Hwang D, et al. Age-associated increase in PGE2 synthesis and COX activity in murine macrophages is reversed by vitamin E. *American Journal of Physiology-Cell Physiology*. 1998;275(3):C661-C8.
9. ElAttar T, Lin H. Effect of vitamin C and vitamin E on prostaglandin synthesis by fibroblasts and squamous carcinoma cells. *Prostaglandins, leukotrienes and essential fatty acids*. 1992;47(4):253-7.
10. Avant R. Dysmenorrhea. *Primary care*. 1988;15(3):549-59.
11. laghmai M, Mir teimouri M, Mokhtari M, Mohammadi M. Comparison of Mefenamic acid / Vitamin E and Mefenamic acid effect on primary dysmenorrhea. *Iran J Fertil Steril*. 2005;6:187–93.
12. Yaghmaei M, Mokhtari M, Mohammadi M. The comparison of the therapeutic effect of Mefenamic acid and Mefenamic acid plus vitamin E on severity of pain in primary dysmenorrhea. *Journal of Reproduction & Infertility*. 2005;6(2).
13. Ziaei S, Faghihzadeh S, Sohrabvand F, Lamyian M, Emamgholy T. A randomised placebo-controlled trial to determine the effect of vitamin E in treatment of primary dysmenorrhoea. *BJOG: An International Journal of Obstetrics & Gynaecology*. 2001;108(11):1181-3.
14. Nasehi M, Sehhatie F, Zamanzadeh V, Delazar A, Javadzadeh Y, Mohammady Chongheralu B. Comparison of the effectiveness of combination of fennel extract/vitamin E with ibuprofen on the pain intensity in students with primary dysmenorrhea. *Iranian journal of nursing and midwifery research*. 2013;18(5).