

ORIGINAL ARTICLE

Comparative Study on Vitamin E & Mefenamic acid versus Mefenamic acid alone on mean reduction in pain in patients with Primary Dysmenorrhea

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ABSTRACT

Background: Pelvic pain around the time of menstruation without any identifiable pathologic lesion present from menarche is called primary dysmenorrhea. The pain is believed to be related to prostaglandin (PG). Women with dysmenorrhoea have a relatively high concentration of PGF 2 alpha in menstrual fluid and suppression of PG synthesis has become the main treatment.

Aim: To compare mean reduction in pain in patients presenting with primary dysmenorrhea given vitamin E & Mefenamic acid versus Mefenamic acid alone.

Results: It was a randomized controlled trial which was conducted in Department of Obstetrics & Gynecology, THQ Raiwind Hospital, Lahore for 6 months duration w.e.f 01/02/2017 to 31/07/2017. In this study, 18(36%) in Vitamin-E group and 21(42%) in Mefenamic acid group were between 15-20 years while 32(64%) in Vitamin-E group and 29(58%) in Mefenamic acid group were between 21-25 years, mean±sd was calculated as 20.86±2.92 and 20.66±2.86 years respectively, mean dysmenorrheal pain at baseline was recorded as 50.06±10.27 in Vitamin-E group and 50.14±10.28 in Mefenamic acid group, p value < 0.754, showing that both groups are insignificant, mean dysmenorrheal pain after treatment was recorded as 20.50±10.04 in Vitamin-E group and 30.22±10.28 in Mefenamic acid group, p value was < 0.002 showing significant difference between the two group, comparison of mean reduction in dysmenorrheal pain after treatment was recorded as 20.56±0.91 in Vitamin-E group and 10.92±0.75 in Mefenamic acid group, p value was < 0.000, showing significant difference.

Conclusion: We concluded that there is a significant mean reduction in dysmenorrhic pain in patients given Mefenamic Acid + Vitamin E as compared to patients given Mefenamic Acid alone.

Keywords: Dysmenorrhic pain, Mefenamic Acid + Vitamin E, mean reduction in dysmenorrhic pain

INTRODUCTION

Painful menstrual cramps without any identifiable pathological reason causing them is known as primary dysmenorrhea. It refers to any degree of perceived cramping pain during menstruation¹.

It is present in approximately 40-50 % of young women. In 15% of young women, its severe forms restrain them from going to work and school. Mild forms requiring no medication is about 30%. Risk factors for dysmenorrhea include nulliparity, heavy menstrual flow, smoking, and depression².

Primary dysmenorrhea can be managed by three approaches, pharmacological, non-pharmacological and surgical. Best documented option by far is the pharmacological approach whereas all other approaches have variable evidences¹. A systematic review of spinal manipulation in the treatment of dysmenorrhea concluded that there is no evidence to suggest effectiveness³.

Higher concentration of PGF2α is present in menstrual fluid of women suffering from primary dysmenorrhea hence inhibition of Prostaglandin synthesis has become the main treatment approach⁴. Better and effective treatment regimens for treatment of primary dysmenorrhea may be developed after complete understanding of pathophysiology of dysmenorrhea⁵.

Vitamin E acts on phospholipase A2 and cyclooxygenase enzymes and inhibits the release of arachidonic acid resultantly inhibiting the conversion of arachidonic acid to PG.⁶ Daily administration of 500 IU of Vitamin E in primary dysmenorrhoea significantly reduces the severity of pain.

In a study it was found that the group who received Mefenamic Acid and Vit E had mean pain intensity of 48.53±17.52 whereas the group who received Mefenamic Acid and placebo had pain intensity of 25.94±21. This difference in pain relief between two groups was significant with p < 0.001⁷.

The rational of this research work is to find out the efficacy of Mefenamic acid alone and vitamin E with Mefenamic Acid in patients with primary dysmenorrhoea in Jinnah Hospital Lahore for expediting the reduction of pain because a large number of patients are coming to Jinnah Hospital Lahore with the history of primary dysmenorrhea.

The objective of the study was to compare mean reduction in pain in patients presenting with primary dysmenorrhea given vitamin E & Mefenamic acid versus Mefenamic acid alone.

Operational definitions

Education in pain: It was measured by subtracting the pain score (measured on VAS) at time of 2nd menstruation cycle from baseline pain score (measured on VAS).

METHODOLOGY

This was a randomized controlled trial conducted at Department of Obstetrics & Gynecology, THQ Raiwand Hospital, Lahore for six months. Sampling was done by Non probability purposive sampling. Sample size calculated was 100 patients; 50 patients in each group with 95% confidence level, 80% power of test and taking mean reduction in pain i.e. 48.53±17.52 in patients given Mefenamic acid+vitamin E and 25.94±21 in patients given Mefenamic acid alone.

Inclusion criteria: Patients with age between 15-25 year, having Primary Dysmenorrhoea (as per operational definitions), complain of pelvic pain within two days before start of menstruation and three days in menstrual cycle along with pain measurement of 40-100cm on visual analogue scale of 100cm were included in study.

Exclusion criteria: Patients already taking Vitamin E therapy and having secondary dysmenorrhoea like fibroid, endometriosis, adenomyosis and ovarian cyst on ultrasound were excluded from study.

Data collection procedure: All patients attending Out Patient Department of THQ Raiwand Hospital, Lahore fulfilling inclusion/exclusion criteria were included in the study. Informed consent was obtained from the patients to include their data in the

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study. Before the start of therapy, the patients' information i.e. demographic history name, age, address and baseline pain score on VAS was recorded. Two groups were formed i.e Vitamin-E group & Mefenamic acid group by random allocation using lottery method. Vitamin-E group was given Mefenamic Acid 400mg with Vitamin-E 400IU and Mefenamic acid group was administered mefenamic acid 400mg alone at the start of menstrual cycle. The pain was measured by subtracting the pain score (measured on VAS) at time of 2nd menstruation cycle from baseline pain score (measured on VAS). All this information was recorded as per pre-designed proforma.

Data analysis: Data was entered and analyzed through SPSS version 10, baseline dysmenorrheal-pain and pain at 2nd cycle was calculated as mean±S.D. Then mean pain at second menstruation was subtracted from baseline mean pain score and reduction of mean pain score was calculated. t-test was used to compare mean reduction in pain. P value ≤0.05 was taken as significant.

RESULTS

A total of 100 cases fulfilling the inclusion/exclusion criteria were enrolled to compare mean reduction in pain in patients presenting with primary dysmenorrhea. Vitamin-E group was given vitamin E plus Mefenamic acid whereas Mefenamic acid group was given Mefenamic acid alone.

Age distribution of the patients In Vitamin-E group and Mefenamic acid group showed that 18(36%) in Vitamin-E group and 21(42%) in Mefenamic acid group were between 15-20 years while 32(64%) in Vitamin-E group and 29(58%) in Mefenamic acid group were between 21-25 years. Mean±sd was calculated as 20.86±2.92 and 20.66±2.86 years respectively (Table 1).

Mean dysmenorrheal pain at baseline was recorded as 50.06±10.27 in Vitamin-E group and 50.14±10.28 in Mefenamic acid group, p value was <0.754, showing both groups are insignificant (Table 2).

Mean dysmenorrheal pain after treatment was recorded as 20.50±10.04 in Vitamin-E group and 30.22±10.28 in Mefenamic acid group, p value was <0.002, showing significant difference between the two group (Table 3).

Comparison of mean reduction in dysmenorrheal pain after treatment was recorded as 20.56±0.91 in Vitamin-E group and 10.92±0.75 in Mefenamic acid group, p value was <0.000, showing significant difference between groups (Table 4).

Table 1: Age distribution (n=100)

Age (in years)	Vitamin-E group (n=50)	Mefenamic acid group (n=50)
15-20	18(36%)	21(42%)
21-25	32(64%)	29(58%)
Total	50(100%)	50(100%)
Mean±SD	20.86±2.92	20.66±2.86

Table 2: Mean dysmenorrheal pain at baseline (n=100)

Mean Pain Score	Vitamin-E group (n=50)	Mefenamic acid group (n=50)
	50.06±10.27	50.14±10.28

P value < 0.754

Table 3: Mean dysmenorrheal pain after treatment (n=100)

Mean Pain Score	Vitamin-E group (n=50)	Mefenamic acid group (n=50)
	20.50±10.04	30.22±10.22

P value < 0.002

Table 4: Comparison of mean reduction in dysmenorrheal pain after treatment (n=100)

Mean Pain Score	Vitamin-E group (n=50)	Mefenamic acid group (n=50)
	20.56±0.91	10.92±0.75

P value < 0.000

DISCUSSION

The reason behind the current study was to determine the efficacy of Mefenamic acid alone (being the conventional treatment) and vitamin E with Mefenamic Acid in patients with primary dysmenorrhoea in Jinnah Hospital Lahore for expediting the reduction of pain because a large number of patients are coming to us with the history of primary dysmenorrhea.

In our study, 18(36%) in Vitamin-E group and 21(42%) in Mefenamic acid group were between 15-20 years while 32(64%) in Vitamin-E group and 29(58%) in Mefenamic acid group were between 21-25 years. Mean±SD was calculated as 20.86±2.92 and 20.66±2.86 years respectively, mean dysmenorrheal pain at baseline was recorded as 50.06±10.27 in Vitamin-E group and 50.14±10.28 in Mefenamic acid group, p value was < 0.754, showing that both groups are insignificant, mean dysmenorrheal pain after treatment was recorded as 20.50±10.04 in Vitamin-E group and 30.22±10.28 in Mefenamic acid group, p value between two groups was significant with value < 0.002, comparison of mean reduction in dysmenorrheal pain after treatment was 20.56±0.91 in Vitamin-E group and 10.92±0.75 in Mefenamic acid group, p value was >0.000, showing significant difference between the two group.

Our findings are in agreement with a study in which it was found that the group who received Mefenamic Acid and Vit E had mean pain intensity of 48.53±17.52 whereas the group who received Mefenamic Acid and placebo had pain intensity of 25.94±21. This difference in pain relief between two groups was significant with p<0.001⁷.

In another study by Pakniat *et al*, it was found that Vitamin E significantly reduced average pain score (VAS) as compared to group taking mefenamic acid with p value < 0.05⁸.

Another study by Ziaei *et al*⁹ confirms that there is a significant decrease in average pain both with Vitamin E and placebo but more decrease in pain was reported with Vitamin E. No adverse effects were seen with Vitamin E.

Similarly another study by Ziaei in revealed that on administration of placebo, initial average pain score of 6/10 (VAS) did not change but decreased to 3/10 at two months and 0.5/10 at four months with Vitamin E. On estimation of duration of pain, it was averaged 18 hours initially and placebo did not change the duration at all but on administration of Vitamin E, duration of pain decreased to 4 hours at two months and 2 hours at 4 months¹⁰.

In our study, we observed a significant decrease in menstrual blood loss also. The limitation of our study was that no adverse events were included, but we found no complaints during this trial. These data suggest that vitamin E represents a safe and effective treatment for primary dysmenorrhoea. However, initially smaller doses of Vitamin E may be administered for a few days before and during the periods and no longer.

CONCLUSION

We concluded that there is a significant mean reduction in dysmenorrhic pain in patients given Mefenamic Acid + Vitamin E as compared to patients given Mefenamic Acid alone.

Contribution of authors: **FS:** Conception of work, Designed research methodology, Literature search, Data collection, analysis, interpretation, Drafting of manuscript, Critical review and Final approval of manuscript, **MF:** Conception of work, Designed research methodology, Literature search, Data collection, analysis, interpretation, Drafting of manuscript, Critical review and Final approval of manuscript, **AMR:** Conception of work, Designed research methodology, Literature search, Data collection, analysis, interpretation, Drafting of manuscript, Critical review and Final approval of manuscript, **SM:** Conception of work, Designed research methodology, Literature search, Data collection, analysis, interpretation, Drafting of manuscript, Critical review and Final approval of manuscript, **AF:** Conception of work, Designed research methodology, Literature search, Data collection, analysis, interpretation, Drafting of manuscript, Critical review and Final approval of manuscript.

approval of manuscript, **AJ**, Conception of work, Designed research methodology, Literature search, Data collection, analysis, interpretation, Drafting of manuscript, Critical review and Final approval of manuscript

Conflict of interest: None to declare

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