



Evening Primrose Oil and Vitamin E in Mastalgia Which Is Better?

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ABSTRACT

Objective: To evaluate the efficacy of evening Primrose oil (EPO) and vitamin E in the management of mastalgia.

Design and Department: A single blind study carried out from June 2010 to Jan 2011 in Sher-I-Kashmir Institute of Medical Sciences, Srinagar.

Patients: A total of 67 patients with moderate to severe breast pain were included in this study.

Methodology: After clinical evaluation, investigations and informed consent all patients were assigned to two groups alternatively. Mastalgia in all patients was gauged before and during the treatment according to the Cardiff Breast Pain Score (CBS) for a period of 4 months.

Group I (n=33) were given evening Primrose oil 1 gram once daily with meals and Group II (n=34) patients were given cap. Vitamin E 400 mg once daily for 4 months. Patients were followed at 4, 8, and 16 weeks.

Result: The overall response of evening Primrose oil was 60.6% in contrast to 47.07% response with vitamin E.

Conclusion: Evening Primrose oil as compared to vit. E has a role in management of mastalgia though statistically there was no difference between these two groups in our study.

Keywords: Evening Primrose oil (EPO), Vitamin E and mastalgia.

Introduction

Breast pain is a common cause of anxiety among women and frequently leads to primary care clinic for consultation¹.

Mastalgia is a common and enigmatic condition; the cause and optimal treatment are still inadequately defined. It may be severe enough to interfere with its effect on quality of life often is underestimated².

The management of mastalgia consists of classification into various pattern, reassurance, drug therapy for severe cases and rarely surgery. Differentiation into cyclic and noncyclic pattern on a simple pain chart is useful for objective assessment of pain severity and appropriate drug therapy and subsequent monitoring of response.

Although the treatment for mastalgia has already been studied extensively, highly effective therapies are still lacking³

Vitamin E and evening Primrose oil are examples of commonly used dietary supplements for management of cyclic mastalgia that have been evaluated.

Several vitamins have been proposed as potential treatment for breast pain including vit. B₆ and vit. E. of these vitamin E is used most commonly for breast pain. The mechanism proposed include its potential to alter steroidal hormone production to correct abnormal serum cholesterol, lipoprotein distribution and to function as antioxidant.

Evening Primrose oil⁴ plant is extracted from seeds of Evening Prim rose plant (*Oenothera* Bennis). Its oil is thus a natural product rather a drug, rich in essential fatty acids like Linolenic acid. The body converts Linolenic acid into a hormone like substance Prostaglandin especially Pg E₁ that helps in the reduction of inflammatory cells⁵. The product is usually prescribed in the dose of 500 mg twice daily.

The purpose of this study was to compare the results of vit. E and evening prim rose oil, to evaluate the efficacy and pain control in women with mastalgia.

Material and Methods

This prospective experimental study was carried out on 87 patients, presenting with moderate to severe breast pain at the surgical outpatient department of Sher-I-Kashmir Institute of Medical sciences Srinagar from June 2010 to Jan 2011

Female patients between 20 and 42 years of age were included in this study. The following patients were excluded from study:

- Patients taking Phenothiazines, estrogen therapy, spironolactone, anticonvulsants and lithium
- Carcinoma breast
- Breast abscess and mastitis
- Nipple discharge
- Lactating and pregnant females

f) Patients who were already taking evening Primrose oil or Vit. E

g) Patients who have undergone breast surgery

A thorough history was obtained and physical examination was carried out on each patient. USG and mammography when necessary were done to exclude benign disease and to exclude occult cancer.

A Proforma to collect the data was filled for each patient. In addition breast pain chart was provided, which each patient was required to fill each day for 4 months for classification, type and severity of breast pain.

The patients were assessed by Cardiff Breast pain score

CBS 1	An excellent response with no residual pain
CBS 2	A substantial response but with some residual pain considered by patients to be bearable and not affecting sleep and daily routine
CBS 3	A poor response with substantial residual pain affecting sleep and daily routine
CBS 4	No beneficial effect at all

After taking informed consent about the response of treatment patients were allocated to two groups: Group I had 33 patients and Group II had 34 patients.

Group I: was given Cap Prim rose oil 1000mg once daily with meals for 4 months.

Group II: was given Cap Vitamin E 400mg once daily with meals for 4 months.

Follow-up of patients were scheduled at 4, 8, and 16 weeks. Any side effects of the drug were enquired and recorded from each patient on their follow-up. Patients who were lost in follow-up were not included in the study.

Pain scores were measured and any decrease in pain was used to compare the three groups.

All the data were analyzed a p value of less than .05 was taken as significant.

Results

The mean age was 32 years; the youngest patient was 19 years old while oldest was 42 years old. 47 patients had bilateral and 20 patients had unilateral breast pain.

On evaluating the Breast pain chart revealed that 50 patients had cyclic mastalgia and 17 patients had noncyclic mastalgia.

The distribution of pain as shown in Table 1 in different groups

Type of pain	Group I	Group II
Cyclic mastalgia	23 (69.69%)	27 (79.41%)
Noncyclic mastalgia	10 (30.30%)	7 (20.58%)

The patients were followed-up at 4, 8, and 16 weeks. It was observed that in group I (EPO) at 4 weeks time 4 patients (12.12%) and 9 patients (27.27%) had CBS 1 and 2 respectively. Whereas in group II (cap vit E) 3 patients (10.34%) and 8 patients (23.52%) had CBS 1 and 2 response at 4 weeks follow-up. Out of 33 patients of group I (EPO) the response observed were:

At 8 weeks CBS 18 patients (24.24%) CBS 2 10 patients (30.30%)

At 16 weeks CBS 19 patients (27.27%) CBS 2 11 patients (33.33%)

Whereas in group II (cap vit E) the response observed was:

At 8 weeks CBS 16 patients (17.64%) CBS 2 9 patients (26.47%)

At 16 weeks CBS 17 patients (20.58%) CBS 2 9 patients (26.47%)

The response of patients in different groups at 4 weeks

Grade CBS	Group I (n=33)	Group II (n=34)
CBS 1	4 (12.12%)	3 (8.82%)
CBS 2	9 (27.27%)	8 (23.52%)
CBS 3	7 (21.21%)	9 (26.47%)
CBS 4	13 (39.39%)	14 (41.17%)

Chi square =0.47

p value =0.92

The response of patients in different groups at 8 weeks

Grade CBS	Group I (n=33)	Group II (n=34)
CBS 1	8 (24.24%)	6 (17.64%)
CBS 2	10 (30.30%)	9 (26.47%)
CBS 3	6 (18.18%)	7 (20.58%)
CBS 4	9 (27.27%)	12 (35.29%)

Chi square =0.82

p value =0.84

The response of patients in different groups at 16 weeks

Grade CBS	Group I	Group II
CBS 1	9 (27.27%)	7 (20.58%)
CBS 2	11 (33.33%)	9 (26.47%)
CBS 3	6 (18.18%)	7 (20.58%)
CBS 4	7 (21.21%)	11 (32.35%)

Chi square =1.40

p value =0.70

At the end of 16 weeks, it was observed in group I, 6 patients had mild side effects like headache, abdominal bloating, and indigestion, while no side effects were observed in group II.

Side effects of drugs

Side effects	Group I	Group II
Headache	1	-
Nausea	3	-
Abdominal bloating	2	-

Our study observed that there was some improvement in breast pain in both groups at the end of 16 weeks but difference in improvement between two groups was not statistically significant, as p value of less than 0.05 was taken as significant.

Discussion

Mastalgia is the commonest breast symptom presenting to general physician and breast surgeon alike⁶. Most of the patients (75-85%) require no treatment, in the remaining patients pain remains constant and interfered with day today activities requiring some treatment⁷.

Assessing the efficacy any treatment can be difficult for many reasons a placebo effect, varying patients compliance with treatment, subjective reporting and also because mastalgia can resolve spontaneously during treatment⁸.

EPO has been widely used in west as first line therapeutic option⁹. In our study, comparison was done between evening prim rose oil and vit E for a period of 4 months.

We observed that there was some improvement in mastalgia in EPO group as compared to vit. E, though statistically it was not significant.

The overall effectiveness of EPO and vit E at the end of 4 months having CBS 1 and 2 were 60.6 % and 47.05%. There is variable response of vit E in relieving breast pain and results are conflicting in various studies.

In one study of double blind placebo controlled cross over trial received 600 mg of placebo and alpha-tocopherol acetate for 3 months by Meyer¹⁰ et al found no subjective or objective effects after treatment and were of the view that vit E is not beneficial in the treatment of benign breast disease.

Similar observations were made by Emster¹¹ et al and London R S¹² et al and were also of the view that vit E had no beneficial effect in the management of mastalgia. Whereas study conducted by Parsay¹³ et al found vit E to be effective in the treatment of mastalgia and considered vit E a safe alternative to hormonal therapies currently being used in the treatment of mastalgia.

A comparative study was done by Nahid Fathizadeh¹⁴ et al between evening prim rose oil and vit E and found cap prim rose oil is effective as compared to vit E, which was also observed in our study.

A double blind randomized placebo controlled trial was conducted by Pruthi S¹⁵ et al to evaluate the effectiveness of vit E, evening prim rose oil and the combination of EPO and vit E for pain control in women with cyclic mastalgia showed a trend towards a reduction of pain with vit E and EPO individually and in combination.

A similar double blind study was conducted by Alvandi Pour M¹⁶ et al and showed that vit E and evening prim rose oil has same therapeutic effect in the treatment of cyclic mastalgia.

Conclusion

Additional research is needed improve over understanding of breast pain and the care of women with moderate to severe symptoms that affect activities of daily life.

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