

# Mastalgia – Use Of Evening Primrose Oil In Treatment Of Mastalgia

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## Abstract

Mastalgia is a common clinical symptom, which 70% of women face at some stage of their lives. Evening Primrose oil in form of capsules is being extensively used for treatment of moderate to severe mastalgia. The objective of this study was to assess the efficacy of Evening Primrose oil in the treatment of mastalgia. We studied 89 female patients presenting with breast symptoms, out of which 11 patients were lost to follow-up, from August 2008 to August 2009 at the surgical out-patient department of SKIMS, Srinagar. Patients were assessed and treatment was given by reassurance, low fat diet, methyl-xanthine restricted diet and dietary supplementation of Evening Primrose oil 1000 mg/day. Response was assessed by visual analog pain score. Response to treatment was assessed at 3 and 6 months. Some response to treatment was reported in 74.44% of patients whereas 26.66% showed no response.

## INTRODUCTION

Breast pain (mastalgia) is a common cause of anxiety<sup>1</sup> among women and frequently leads to primary care clinic for consultation.

Some breast pain or discomfort is experienced by about two thirds of women<sup>2</sup> during the premenstrual phase.

This pain is mild, lasts for a short time in the premenstrual phase, but more importantly, it resolves with menstruation. Therefore, it can be considered within the spectrum of normal physiology. The development of severe pain which may last for most of the menstrual cycle is considered as abnormal and may significantly interfere with patient's every day activities.

Breast pain<sup>3</sup> is typically approached according to its 3 classifications as cyclic mastalgia, non-cyclic mastalgia and extramammary (non-breast) pain.

Cyclic mastalgia is a breast pain that has clear relationship to the menstrual cycle. Non-cyclic mastalgia may be constant or intermittent but not necessarily associated with menstrual cycle and often occurs after the menopause.

Extra-mammary pain arises from the chest wall from other sources and is interpreted as having the cause within the breast. Cyclic breast pain or mastalgia occurs in about 70% of the female population<sup>4</sup> and after exclusion of breast

cancer and proper re-assurance, only 15% of patients initially presenting will require treatment using Cap. Evening Primrose oil, bromocriptine and danazol. Some 77% of patients treated can obtain useful relief from their symptoms. Cap. Evening Primrose oil is an extract from a plant which is found in many parts of North America. EPO is omega-fatty-acid-rich oil, containing both linolenic acid (LA) and gamma-linolenic acid (GLA). EPO contains 74% LA, 11% oleic acid, 6% palmitic acid, 2% stearic acid and 9% GLA.

It has been seen that women with breast pain have usually low concentration of GLA and metabolites.

Cap. Evening Primrose oil is a dietary supplement and has been investigated in depth for its effectiveness for conditions that are associated with deficiency in essential fatty acids.

EPO has a good safety profile with mild side effects and rare serious adverse events. EPO should not be taken during pregnancy, prior to surgery, in patients at risk for seizures or taking phenothiazines and related medications, anti-platelets, thrombolytics, low molecular weight heparin or anticoagulants. The German Commission E has not approved the use of EPO for any condition.

The management of mastalgia consists of classification into various patterns, re-assurance, drug therapy for severe cases and, rarely, surgery.<sup>6</sup> Differentiation into cyclical and non-

cyclical pattern on a simple pain chart is useful for objective assessment of pain severity and for selection of approved drug therapy and subsequent monitoring of response.

### MATERIAL AND METHODS

This prospective study was carried out on 89 female patients presenting with mild to severe breast pain at the surgical out-patient department of SKIMS, Srinagar, from August 2008 to August 2009.

Female patients between 17 and 40 years of age were included in the study.

The following patients were excluded from the study: patients with carcinoma of the breast; patients on anticonvulsants, phenothiazines or lithium; patients with breast abscess, mastitis or nipple discharge; lactating and pregnant patients; patients on estrogen therapy, digoxin, anticoagulation; and patients with breast trauma or after breast surgery.

During the first visit, a detailed clinical history and physical examination was done. USG and FNAC were done only in patients having lumps to rule out breast cancer. Mammography was done in patients above 30 years of age.

Patients were given capsule Evening Primrose oil 500mg twice daily with meals for 6 months.

Data was collected on a pre-designed Performa by a resident. In addition, a breast pain chart was provided to the patient, which was to be filled in by the patient each day for 6 months to assess her severity of pain. The response to treatment was assessed by using a visual analogue pain score to assess the severity of pain at each follow-up to categorize between cyclical and non-cyclical mastalgia as follows:

Grade I - Excellent

Grade II - Substantial

Grade III - Poor

Grade IV - No response

The purpose of the study was to assess the value of Cap. Evening Primrose oil in the management of cyclic and non-cyclic breast pain.

Follow-up of patients was scheduled at 3 months and at 6 months.

During this study, all patients were evaluated to determine

the type of mastalgia, its duration, severity and response.

Treatment was initiated after complete assessment, by reassurance, advice for low-fat diet and dietary supplementation with Cap. Evening Primrose oil 1000mg/day for 6 months.

### RESULTS

The mean age was 26.77 with a standard deviation (SD) of 5.81. The youngest patient was 17 years of age while the oldest was 40 years. Out of 89 patients, 11 were lost to follow-up.

Fifty patients had bilateral mastalgia, whereas 28 patients had unilateral breast pain.

Characterization of type of pain by evaluating the breast pain chart revealed that 58 patients had cyclical mastalgia and 20 patients had non-cyclical mastalgia.

#### Figure 1

Table 1: Distribution of type of pain in patients (n=78)

Type of pain	No. of patients
Cyclic mastalgia	58 (74.35%)
Non-cyclic mastalgia	20 (25.6%)

Patients were assessed for severity of pain by using a visual analog pain score in which 28 patients (35.89%) had mild, 35 patients (44.87%) moderate and 15 patients (19.23%) severe pain.

At the end of three months, the patients were reviewed and the response to treatment was as follows:

In the cyclical mastalgia group (58 patients),

23 patients (39.65%) had grade I (excellent) response,

17 patients (29.31%) had grade II (substantial) response,

12 patients (20.68%) had grade III (poor) response, and

6 patients (10.34%) had grade IV (no) response to treatment.

In the non-cyclical mastalgia group (20 patients),

9 patients (45%) had grade I (excellent) response,

6 patients (30%) had grade II (substantial) response,

3 patients (15%) had grade III (poor) response, and

2 patients (10%) had grade IV (no) response to treatment.

**Figure 2**

Table 2: 3-month follow-up (n=78 patients)

Type of pain	Grade I	Grade II	Grade III	Grade IV
Cyclical mastalgia (n=58)	23 (39.65%)	17 (29.31%)	12 (20.68%)	6 (10.34%)
Non-cyclical mastalgia (n=20)	9 (45%)	6 (30%)	3 (15%)	2 (10%)

At the end of 3 months, it was observed that in the cyclic mastalgia group, 18 patients (31.02%) showed grade III and grade IV response to treatment and there were 5 patients (25%) in the non-cyclical mastalgia group who showed grade III and grade IV response to treatment.

These patients did not show any remarkable improvement during the treatment. They were re-assessed and were advised to have fresh fruits and vegetables and to wear proper fitting and supporting undergarments.

The patients were advised to continue Cap. Evening Primrose oil 1000mg/day for 6 months.

At the end of 6 months, the response to treatment was as follows:

In the cyclical mastalgia group (58 patients),

24 (41.37%) patients had grade I (excellent) response, 18 (31.03%) patients had grade II (substantial) response, 10 (17.24%) patients had grade III (poor) response, and 6 (10.34%) patients had grade IV (no) response to treatment.

In the non-cyclical mastalgia group (20 patients)

9 (45%) patients had grade I (excellent) response  
 7 (35%) patients had grade II (substantial) response  
 2 (10%) patients had grade III (poor) response  
 2 (10%) patients had grade IV (no) response to treatment.

**Figure 3**

Table 3: 6-month follow-up (n=78 patients)

Type of pain	Grade I	Grade II	Grade III	Grade IV
Cyclical mastalgia (n=58)	24 (41.37%)	18 (31.03%)	10 (17.24%)	6 (10.34%)
Non-cyclical mastalgia (n=20)	9 (45%)	7 (35%)	2 (10%)	2 (10%)

At the end of 6 months, it was observed that in the cyclical mastalgia group, 24 patients (41.37%) had grade I response, 19 patients (32.75%) patients had grade II response and in the non-cyclical mastalgia patients, 9 (45%) had grade I

response and 7 (35%) had grade II response. The overall response to treatment in cyclical and non-cyclical mastalgia was 75.64%.

It was, however, observed that 16 patients (27.58%) belonging to the cyclical mastalgia group had grade III and grade IV response and 4 patients (20%) in the non-cyclical group showed grade III and grade IV response.

Thus, overall 25.64% patients showed poor to no response to treatment.

The patients belonging to grade III and grade IV, in spite of repeated reassurance, diet modification, wearing of proper fitting and supporting underclothing and dietary supplementation of Cap. Evening Primrose oil, did not show any improvement. These patients were anxious and stressed out, and were put on Tab. Danazol 100mg (anti-gonadotropin) as a second line of treatment, along with NSAIDS topical gels, after completion of our study.

**DISCUSSION**

Mastalgia (breast pain) affects up to 77% of women at some time in their lives and is so common that it is considered part of the normal body process, rather than a disease.

Mastalgia may be accompanied by tenderness, fullness, lumpiness or a noticeable increase in breast size. For many women, mastalgia is a cause of significant discomfort<sup>8</sup> and anxiety but is not usually a sign of breast cancer.

Differentiating breast cancer from benign breast conditions is a task that requires access to clinical examination, radiology and pathology.

Any woman with breast symptoms/significant mastalgia requires breast imaging. USG and mammography are indicated, depending on age and clinical findings. Women older than 35 years of age<sup>10,11</sup> should have a mammogram even if physical examination is normal, to detect the rare presence of malignancy.

In our study, mammography was also advised in patients above 35 years of age. The patients were treated with reassurance, advice on adhering to low-fat diet and avoidance of methyl-xanthine diets like caffeine, chocolates, cocoa etc.

We found that in mild to moderate mastalgia reassurance is the first protocol of treatment. However, the value of methyl-xanthine restriction has not been proved.<sup>7,8,12</sup>

Our study comprised 58 patients (74.35%) having cyclical

mastalgia and 20 patients (25.6%) having non-cyclic mastalgia, showing that cyclic mastalgia is more common than non-cyclic mastalgia, which was also noted by Uma<sup>13</sup>.

It was observed in our study that there was overall 75.64% of response to Cap. Evening Primrose oil at the end of 6 month, whereas 97% of response was seen by Cheung<sup>14</sup>.

However, low response was noted by Rana et al.<sup>15</sup> as EPO was given only for a period of 2 months which is in contrast to our study where duration of treatment was 6 months.

Keeping in mind that EPO is a form of dietary manipulation, having slow onset of action<sup>8</sup>, its optimal effect appears in 3 to 6 months.<sup>2,16</sup>

Results and clinical screening of assessing the efficacy of Cap. Evening Primrose oil in the treatment of mastalgia are conflicting.

Whereas use of Cap. Evening Primrose oil as a first line of treatment was advocated by Gateley et al.<sup>17</sup>, conversely, randomized trials conducted by Blommers et al.<sup>18</sup> using control oil, fish oil, wheat germ oil, Primrose oil and corn oil observed that neither fish oil, nor Evening Primrose oil showed benefit over corn oil and wheat germ oil.

Similarly, a double-blind randomized trial by Goyal and Mansel<sup>19</sup> to see the efficacy of Cap. Primrose oil, regardless of whether or not antioxidant vitamins were present, did not appreciate the efficacy of Cap. Primrose oil, which did not differ from placebo fatty acids.

The patients who showed poor to no response to treatment had moderate to severe mastalgia, the overall rate of no response was 25.64%. These patients were put on Tab. Danazol 200mg as a second<sup>19</sup> line of treatment after completion of our study and were given topical non-steroidal anti-inflammatory<sup>21</sup> gel to be applied directly on the breast to get relief from pain.

A comparative study<sup>16</sup> was conducted by Qureshi et al. to see response of pain to NSAIDs and Cap. Evening Primrose oil. They observed that 68% had relief with EPO and 96% with NSAIDs.

Mastalgia is a common problem among perimenopausal women and those with severe and protracted symptoms merit proper treatment.

### CONCLUSION

The purpose of this study was to assess the efficacy of Cap.

Evening Primrose oil in mastalgia.

We observed that Cap. Evening Primrose oil can be used as first line of treatment in mild to moderate mastalgia; however, its efficacy for moderate to severe mastalgia remains doubtful.

Therefore, further studies are required to improve our understanding of breast pain and management of patients with moderate to severe symptoms of mastalgia.

### References

1. Mittel AV, Dibas FM: Clinical management of breast pain: a review. *Obstet Gynecol Surg*; 2001; 57(7): 451-61.
2. Smith RL, Pruthi S, Fitzpatrick LA: Evaluation and management of breast pain. *Mayo Clin Proc*; 2004; 79: 353-372.
3. Bashir MA: Mastalgia. *Br J Clinical Pract*; 1990; 44: 454-6.
4. Gateley CA, Mansel RE: Management of cyclical breast pain. *Br J Hosp Med*; 1990; 43(5): 330-2.
5. Artz MB: Evening primrose oil. *Forensic Science and Medicine Herbal Products*, 2nd edition. Toxicology and Clinical Pharmacology. ISBN 978-1-158829-313-8, Oct. 5, 2007: 211-251.
6. Maddox PR, Mansel RE: Management of breast pain and nodularity. *World J Surg*; 1981; 13: 699-705.
7. Brennan M, Houssami N, French J: Management of benign breast conditions. *Breast series, Clinical practice. Aust Fam Physician*; 2005; 34: 253-5.
8. Marrow M: The evaluation of common breast problems. *Am Fam Physician*; 2000; 61(8): 2371-8.
9. Sharma A, Banderi R, Gilbert D, Sharma AE: Benign and malignant breast disease presenting to Bhaktapur Cancer Hospital. *Kathmandu University Medical Journal*; 2005; 3(4) issue 12: 384-387.
10. Vaidyanathan L, Barnard K, Elnicki DM: Benign breast disease: when to treat, when to reassure, when to refer. *Cleve Clin J Med*; 2002; 69: 5.
11. Hindle W, Mokbel K: *Glob libr women's med* (ISSN: 1756-2228) 2008; DOI 10.3843/GLOWM.10017.
12. Uma Krishnaswamy: Profile of benign breast disease in urban India. *Indian J Surg*; 2003; 65(2): 178-181.
13. Uma Krishnaswamy: Refractory mastalgia or inadequately treated mastalgia? *Indian J Surg*; 2004; 66: 89-92.
14. Cheung KL: Management of cyclical mastalgia in oriental women pioneer experience of using gamolenic acid (Efamast) in Asia. *ANZ Journal of Surgery*; 1999; 69(7): 492-494.
15. Rana NA, Javaid RH, Waqas A, Intisar-ul-Haq: Mastalgia: comparison of topical non steroidal anti-inflammatory drugs with evening primrose oil. *Professional Med J*; 2009; 16(2): 239-296.
16. Qureshi S, Sultan N: Topical nonsteroidal anti-inflammatory drugs versus oil of evening primrose in the treatment of mastalgia. *Surgeon*; 2005; 3(1): 7-10.
17. Gateley CA, Miers M, Mansel RE, Hughes LE: Drug treatments for mastalgia: 17 years experience in the Cardiff Mastalgia Clinic. *J R Soc Med*; 1992; 85: 12-5.
18. Blommers J, deLange-De Klerk ES, Kuik DJ, Bezemer PD, Meijer S: Evening Primrose oil and fish oil for severe chronic mastalgia. *Obst and Gynecological Survey*; 2003; 58(5): 317-319.
19. Goyal A, Mansel RE: A randomized multicenter study of

gamolenic acid (Efamast) with or without antioxidant vitamins and minerals in the management of mastalgia. *Breast J*; 2005; 11(1): 41-47.  
20. Irwing AD, Morrisson SL: Effectiveness of topical non-

steroidal anti-inflammatory drugs in the management of breast pain. *J Coll Surg Edinb*; 1998; 43: 158-159.  
21. Faiz O, Fentiman IS: Management of breast pain. *Int J Clinic Pract*; 2000; 54(4): 228-232.

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