

# “Comparing The Clinical Response Of Ormeloxifene, Evening Primrose Oil And Topical Diclofenac For Treatment Of Mastalgia In Benign Breast Disorders”

Dr. Ashish Trehan

Dr. Ashish Moudgil

Dr. Ravi Kale

PG Resident, Department Of General Surgery, Sharda School Of Medical Sciences & Research, Greater Noida-201310, Uttar Pradesh

Assistant Professor, Department Of General Surgery, Sharda School Of Medical Sciences & Research, Greater Noida-201310, Uttar Pradesh

Professor, Department Of General Surgery, Sharda School Of Medical Sciences & Research, Greater Noida-201310, Uttar Pradesh

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## Abstract

Mastalgia, or breast pain, affects up to 75% of women, often raising concerns about breast cancer. This study compares the efficacy of three treatments—ormeloxifene, evening primrose oil (EPO), and topical diclofenac—in reducing pain, nodularity, and lump size associated with benign breast disorders. A comparative study was conducted at Sharda Hospital from May 2023 to April 2024 with 48 patients aged 18–35 years and patients followed up at 4, 12 and 18 weeks. The results demonstrated significant improvement with ormeloxifene, in pain reduction, regression of breast nodularity and fibroadenoma, making it a promising treatment option.

**Keywords:** Mastalgia, benign breast disorders, Ormeloxifene

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## I. Introduction

Mastalgia or breast pain affects up to 75% of women during their lifetime and is the reason for 50% of all referrals to breast clinics.[1] Mastalgia may be cyclical or non-cyclical exacerbation of pain depending on its relation with menstrual cycle. It also raises fear and anxiety of breast carcinoma. Mastalgia is hormone dependant so when estrogen and progesterone levels fall just before menstruation there is a reduction of cellular proliferation in the early follicular phase, leading to respite in pain and engorgement.[2]

The nomenclature of benign breast disease in the past has been confusing owing to the use of a variety of terms namely, fibrosis, adenosis, epitheliosis, fibroadenosis and fibrocystic disease - for clinical patterns of pain, nodularity, benign lumps and nipple discharge. However, such terms do not relate to clinical or histological features. Most benign disorders are derived from minor aberrations of the normal process of development, cyclical hormone related change and involution. To address this confusion, the concept of Aberrations of Normal Development and Involution (ANDI), developed and described by the Cardiff Breast Clinic in the UK, helps in better understanding and treatment of benign breast disease.[3]

The current guideline available for management of mastalgia includes reassurance, physical support (well-fitting brassiere), evening primrose oil (EPO), diclofenac gel and anti-estrogenic drugs.[3]

## II. Materials And Methods

A comparative study was conducted at Sharda Hospital from May 2023 to April 2024. 48 patients aged 18 to 35 years were randomly assigned to one of the three groups. Group A was given capsule EPO 1000 mg three times daily orally, Group B was given tablet ormeloxifene 30 mg one tab on alternate days orally, and Group C used topical diclofenac gel on affected area three times a day for 12 weeks. (p Value <0.05)

### Inclusion criteria

1. Patient having mastalgia with or without lump of less than 5 cm in size / breast nodularity
2. Age 18 to 35 years.

**Exclusion criteria**

1. Giant fibroadenoma (more than 5 cm in size)
2. Breast malignancy.
3. Polycystic ovarian syndrome
4. Liver disease
5. Pregnancy
6. Lactation period for first 6 months
7. Patients on oral contraceptive pills in the last 4 weeks
8. History of breast malignancy or family history of breast malignancy

Along with detailed history, clinical examination and data of patients, following was also collected at the time of initiation of therapy:

1. Pain as per visual analogue scale (VAS).
2. Lucknow Cardiff Scale for breast nodularity.
3. USG scan of the affected breast and axilla and contralateral breast.
4. FNAC of palpable lump.
5. USG pelvis (to rule out PCOS).
6. Investigations- Complete blood count and liver function tests.

Follow up was done at 4, 8 and 12 weeks. At each visit the following was reviewed.

1. Pain as per visual analogue scale (VAS).
2. Lucknow Cardiff Scale for breast nodularity.
3. USG scan of the affected breast and axilla and contralateral breast.
4. Adverse effects were noted.

**III. Results**

The study evaluated 48 patients with mastalgia, distributed across three treatment groups: ormeloxifene (17 patients), evening primrose oil (EPO, 16 patients), and topical diclofenac (15 patients). The mean age of participants was  $27.08 \pm 5.54$  years. The cohort consisted of 20 patients presenting with breast nodularity and 12 patients diagnosed with fibroadenoma. Mastalgia cases were split between cyclical (23 cases) and non-cyclical (25 cases).

**Table 1- Mean VAS scores recorded during research**

Groups	Initial	4 weeks	8 weeks	12 weeks
Ormeloxifene	5.76 ±0.68	0.87 ±0.43	0.23 ±0.14	0.17 ±0.09
Evening primrose oil	5.87 ±0.59	2.17 ±0.92	1.24 ±0.71	1.28 ±0.66
Topical diclofenac	5.86 ±0.71	1.62 ±0.87	1.12 ±0.63	0.98 ±0.44

All groups showed gradual relief in mastalgia. At 12 weeks, ormeloxifene significantly outperformed EPO ( $p = 0.007$ ) and topical diclofenac ( $p = 0.023$ ) in reducing mean VAS scores. The comparison between EPO and topical diclofenac was not statistically significant ( $p = 0.29$ ).

**Table 2 - Response in patients with breast nodularity in different groups**

n=20	Ormeloxifine	EPO	Topical diclofenac
Total patients	8	6	6
Complete resolution	50%	-	-
Partial resolution	50%	33.33%	-
No response	-	66.66%	100%

Nodularity regression (n=20) was most pronounced in the ormeloxifene group, with significant improvement compared to EPO and topical diclofenac. 100% of the patients responded to ormeloxifene while only 33.33% of the patients in EPO arm showed partial resolution. No response recorded in topical diclofenac group.

**Table 3 - Reduction in size of fibroadenoma**

n=12	Ormeloxifene	EPO	Topical diclofenac
Total patients	4	3	5
Complete resolution	50%	-	-
Partial resolution	50%	33.33%	-
No response	-	66.66%	100%

Of the 12 patients with fibroadenomas, ormeloxifene resulted in the highest rates of regression with all patients experiencing reduction in size of fibroadenoma. 33.33% of the patients in EPO arm showed partial resolution and no response was seen in topical diclofenac group.

Adverse effects were seen in 11% (n=2) who reported delayed menses in ormeloxifene arm. EPO caused nausea in 18% of the patients while topical diclofenac resulted in burning sensation at applied area in 6% of the patients.

#### **IV. Discussion**

The findings align with previous studies highlighting the efficacy of ormeloxifene in managing mastalgia in benign breast disorders. Brahmachari S et al studied thirty patients having mastalgia with fibroadenoma. Almost all of the patients were painless in one month with ormeloxifene. Complete dissolution and change in the size of lump was noted in 34%, partial response in 46 % and no changes in 20 %.[4]

Study done by Roy SB et al on 140 patients showed excellent response for mastalgia in ormeloxifene group (84%) compared to EPO group (25%). Nodularity decreased in 80% of patients in ormeloxifene arm and 26% in EPO arm. Additionally, complete resolution of fibroadenoma was noted in 40% of patients with ormeloxifene treatment.[5]

#### **V. Conclusion**

Ormeloxifene is a superior treatment for mastalgia in benign breast disorders. Its efficacy and patient-friendly regimen make it a compelling option for clinical practice.

#### **References**

- [1] Caimcross L. Mastalgia. *Contin Med Ed.* 2010;28(11):504-506
- [2] Kamboj Vp, Ray S, Anand N. Centchroman: A Safe Reversible Postcoital Contraceptive With Curative And Prophylactic Activity In Many Disorders. *Front Biosci (Elite Ed).* 2018;10:1–14.
- [3] O'connell P.R, Mccaskie A.W, Sayers R.D. *Bailey And Love's Short Practice Of Surgery.* 28th Ed. Boca Raton (FL): Crc Press; 2023. P. 918-919
- [4] Brahmachari S, Bhagat V, Patil P, Vasuniya V. Evaluating The Effect Of Ormeloxifene On Multiple Fibroadenomas And Mastalgia. *J Pharm Bioallied Sci.* 2021;13(Suppl 2):S1386–9.
- [5] Roy Sb, Hembram R. A Comparative Study Of Efficacy Of Centchroman And Evening Primrose Oil In Treatment Of Benign Breast Disease. *J Evol Med Dent Sci.* 2018;7(31):3518–24.