

# Efficacy and Safety of Ormeloxifene in Regression of Mastalgia Associated with Fibrocystic Disease of Breast

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**Abstract:** Background: Mastalgia and fibrocystic breast disease is common occurrence in women of reproductive age group. Ormeloxifene is a weak oestrogen receptor (ER) agonist, a strong ER antagonist (SERA) and therefore a selective ER modulator (SERM) used in the treatment of the disease. Aim of study was to see the efficacy and safety of Ormeloxifene in regression of mastalgia associated with fibrocystic breast disease. Material and method: This was prospective trial, conducted in NMCH, Patna from December 2015 to March 2017. Fifty women of age 20-40 year with mastalgia associated with fibrocystic disease of breast with VAS score more than 2 were treated with Ormeloxifene 30mg once daily on alternate days for a period of 3 months. Follow up was done monthly for 3 month and then at 6 month with Visual Analogue Scale (VAS) for pain and for side effect. Results: Total 63 patients were enrolled in the study. 13 patients left during trial. 50 patients completed the trial. The mean age was 34 year. The mean pain level was continuously decreased over 5 visit (4.72 to 0.51) at 24 week. 15 (30%) patients reported oligomenorrhoea. Conclusion: Ormeloxifene showed significant efficacy and safety for the treatment of mastalgia in fibrocystic breast disease.

**Keywords:** Mastalgia, Fibrocystic disease of breast, SERM, Ormeloxifene

## 1. Introduction

Breast pain or mastalgia is one of the most common benign condition of the breast. Approximately 60 to 70 % of women experience some degree of breast pain at some stages of their lives, and in 10 to 20 % of cases, it is severe. The two most common concerns of patients presenting with mastalgia are: the fear of breast cancer and the presence of severe pain that affects a woman's quality of life. Mastalgia is often associated with fibrocystic disease of breast

Fibrocystic breast disease is a common non-cancerous breast disease in women, usually found in women of reproductive age group. FCBD covers a broad range of conditions from painful breasts with solid, lumpy, thickened areas to cysts. Pain from FCBD can occur at any time of cycle. After convincingly ruling out cancer the majority of patients with mastalgia can be managed with reassurance and simple non pharmacological measures. Drug is given when pain is severe or interfering with daily activity of patients

There is considerable debate about drug of choice for management of mastalgia. In my study, I present trial of ormeloxifene.

The objective of the study was to evaluate the efficacy and safety of Ormeloxifene in regression of mastalgia in fibrocystic disease of breast; measured by visual analogue scale (VAS).

## 2. Methods

This was a randomized trial of oral Ormeloxifene 30 mg alternate day for 3 month in patients of 20-40 years of age.

### Inclusion criteria

Women in the age group of 20-40 years with cyclical or non-cyclic breast pain having VAS score more than 2 were considered for the study. Thorough clinical examination of

the breast was done followed by bi-planer mammography. In patients having mammographic finding suggestive of fibrocystic disease were included in the study.

### Exclusion criteria

- Those planning a pregnancy
- Patients taking alternative treatment,
- Lactating women,
- Suspicion of malignancy
- Taking other oral contraceptive pills,
- Women suffering from polycystic ovarian disease,
- Liver and kidney problems

The patients were provided with a detailed information regarding benign nature of breast pain, the currently available therapy with side effects, the potential benefits of Ormeloxifene. Patients were asked to keep a record of their breast pain in a "pain diary". The time of menses was also marked on pain diary. The severity of mastalgia was assessed by visual analogue scale score ranging from 0-10, zero (0) indicating no pain and 10 indicating very severe pain. Ultrasound scan of pelvis and gynecological evaluation was performed to exclude the patients with polycystic ovarian disease and cervical hyperplasia, as Ormeloxifene is known to worsen these conditions.

The patients were given oral Ormeloxifene 30 mg alternate day for 3 month

## 3. Follow-up

The patients were evaluated at one week to assess tolerance to the drug. Subsequently patients were followed at 4 weeks, 8 weeks, 12 weeks and 24 weeks and response to therapy was assessed by VAS score. The drug treatment was continued for a total of 12 weeks and then the patient was followed at 6 month without medication to assess sustained response or recurrence of mastalgia.

**Table 1: Age Distribution**

Age distribution	Number of patients	Percentage
<25 year	6	12
25-30	8	16
30-35	16	32
35-40	20	40
Total-50		100

**Table 2: Types of Mastalgia**

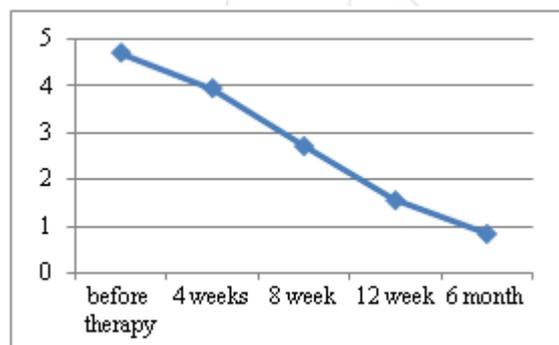
Diagnosis	Number of patients	Percentage
Cyclic mastalgia	38	76%
Non cyclic mastalgia	12	24%
Total	50	100%

**Table 3: Pain Assessment**

Pain score	Before initiating treatment	At 4 week	At 8 week	At 12 week	At 6 month
0	0	0	5	22	35
2	0	8	25	20	12
4	32	35	17	5	0
6	18	7	3	3	0
8	0	0	0	0	0
10	0	0	0	0	0
Total	50	50	50	50	47

**Table 4: Mean Pain Score**

Visit	Mean pain score
At beginning of treatment	4.72
At the end of first month	3.96
At the end of second month	2.72
At the end of third month	1.56
At the end of sixth month	0.51



**Table 5: Side Effect**

Side effect	Number of patients	Percentage
Gastritis	5	10
Menstrual delay	15	30
No side effect	40	80

#### 4. Discussion

Mastalgia in fibrocystic breast disease is common. Mild pain may be managed by reassurance and non pharmacological measures. Patients having moderate to severe pain interfering with day to day activity requires medical treatment. There are many drugs available for treatment of mastalgia. In my study Ormeloxifene used in mastalgia associated with fibrocystic breast disorder.

Ormeloxifene is a novel nonsteroidal, selective estrogen receptor modulator, anticancer and anti-osteoporotic drug formulated by the Central Drug Research Institute,

Lucknow, India. Ormeloxifene has weak estrogen agonistic activity in some tissues like bones, and potent anti-estrogenic action in uterus and breast. It is devoid of progesterone, androgenic and anti-androgenic activities. Ormeloxifene is free from side effects like nausea, vomiting, weight gain and dizziness. Ormeloxifene does not delay return of fertility (after stopping) as it does not disturb ovulation. It has only one adverse effect, delayed menses in less than 10% of cycle. Ormeloxifene is well absorbed when given orally. In target tissues such as endometrium and breast, it competes with estradiol for binding to estrogen receptors and shows an anti-estrogenic activity. The drug is demethylated and about 26% is excreted unchanged in feces. In my study mean age was 34 years. 38 patients reported of cyclical mastalgia and 12 patients reported non-cyclical mastalgia in which patients reported either intermittent pain or pain throughout the cycle without premenstrual aggravation. Before initiating treatment mean pain score was 4.72. 32(64%) patients had VAS score 4 and 18(36%) patients had VAS 6. At 4 weeks mean pain score was 3.96. VAS score of 8 patients (16%) was 2, 35 patients (70%) was 4 and 7(14%) patients was 6. At 8 weeks mean pain score was 2.72, VAS score of 5 (10%) patients was zero, 25 (50) patients was 2, 17(34%) patients was 4 and 3(6%) was 6. At 12 weeks mean pain score was 1.56 and 22(44%) patients were completely relieved of pain with VAS score 0. VAS score of 20(40%) patients was 2, 5(10%) was 4 and 3(6%) was 6. Patients having VAS score of 6 at 12 weeks were given alternative treatment. At 6 month mean pain score was 0.51, 35 (70%) patients reported VAS score 0, 12 (24%) had VAS score 2. Oligomenorrhoea was noted in 15 (30%) of patients and gastritis in 5(10%) of patients.

Vandana Bansal & team in their study on Efficacy of Sevista (Ormeloxifene) in treatment of mastalgia and fibrocystic breast disease reported the mean pain score after three month was 1.21 and after six month (without treatment) it was 0.86.

Uday Kapoor Rajswaroop & team in their study on effectiveness of Centchroman in mastalgia and fibroadenosis reported VAS 2 OR 0 IN 35/51 after 3 months and , complete pain relief in 46 patients out of 51 after 6 month

Sandeep kumar & team in a randomized, double-blind, placebo-controlled trial of ormeloxifene in breast pain and nodularity reported decrease in mean pain score from 5.71 at the start of therapy to 1.39 after 3 month and 0.98 at 6 month

#### 5. Conclusion

Mastalgia and fibrocystic disease of breast are common in women of reproductive age group. Mastalgia can be managed by simple reassurance and non pharmacological measure. Drug are given when pain interferes with quality of life. Ormeloxifene is safe, effective and cheap drug for management of mastalgia

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