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A prospective comparative interventional study of diclofenac gel plus ormeloxifene versus diclofenac gel plus evening primrose oil in the treatment of mastalgia in benign breast diseases.

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Abstract

Background

Mastalgia, a common symptom of benign breast diseases, affects women's quality of life. This study aimed to compare the efficacy of diclofenac gel plus ormeloxifene versus diclofenac gel plus evening primrose oil in the treatment of mastalgia in benign breast diseases.

Methods

The study analyzed 100 female patients aged 18-45 with mastalgia in the Department of General Surgery at BRD Medical College, Gorakhpur, between 2023 and 2024. The patients were divided into two groups: Group A (diclofenac gel + ormeloxifene 30 mg twice weekly for 3 months) and Group B (diclofenac gel + evening primrose oil 1000 mg twice daily for 3 months).

Results

At baseline, both groups had comparable VAS scores (6.76 ± 1.45 in Group A vs. 6.40 ± 1.64 in Group B, $p = 0.248$). At 1 month, VAS scores decreased in both groups (4.30 ± 1.47 in Group A vs. 4.70 ± 1.66 in Group B, $p = 0.205$), with no significant difference. However, at 3 months, the VAS score reduction was significantly greater in Group A (1.36 ± 1.74) compared to Group B (2.84 ± 2.05) ($p < 0.001$), indicating superior pain relief with ormeloxifene. Intra-group analysis showed a significant reduction in pain over time in both groups ($p < 0.001$). A higher proportion of participants in Group A (76.00%) showed significant improvement compared to 40.00% in Group B ($p = 0.001$).

Conclusion

Ormeloxifene, when combined with diclofenac gel, demonstrated superior efficacy in reducing mastalgia symptoms compared to evening primrose oil, indicating its superior treatment option for benign breast diseases.

Recommendation

It recommends individualized treatment based on symptom severity, patient preference, and tolerance. Regular follow-up is recommended for pain relief, adherence, and side effects. Further large-scale studies are needed for validation and standardized treatment protocols.

Keywords: *Mastalgia, Benign Breast Disease, Diclofenac Gel, Ormeloxifene, Evening Primrose Oil*
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Introduction

Breast pain, or mastalgia, is a common complaint among women, often leading to doctor visits due to discomfort and concerns about breast cancer. Around 60-70% of women experience some form of breast discomfort, with 10-20% experiencing severe pain that significantly impacts their daily activities and quality of life. [1-3] Breast discomfort has a significant psychological and social impact, affecting women's sexual activity, physical performance, and social functioning. Studies show that 48% of women with breast complaints report sexual activity issues, 37% physical performance problems, and 10% social functioning issues. Despite benign breast conditions being the primary cause, the need for comfort and appropriate therapy remains crucial. [4,5]

Cyclic mastalgia is a common form of mastalgia, characterized by discomfort associated with the menstrual cycle, usually occurring one to two weeks before menstruation and disappearing with menstruation. It is widespread, bilateral, and can spread to the armpits and upper arms. Women affected by cyclic mastalgia often experience hormonal changes in their 30s and 40s, including higher estrogen and lower progesterone levels. Although it resolves in up to 22% of cases, it still affects around 65% of patients even when treated. [6,7] non-cyclical mastalgia, a third of cases, is confined to one quadrant of the breast and may present as intermittent or continuous discomfort. It is common in perimenopausal women in their 40s and 50s. [8,9]

Extramammary pain, originating from tissues outside the chest, can be a sign of conditions like costochondritis, Tietze syndrome, arthritis, and sliding rib syndrome. Mastalgia, a condition with complex causes, is primarily caused by hormonal abnormalities, including decreased progesterone levels and increased estrogen and prolactin levels. It is also linked to altered fatty acid metabolism, inflammatory processes, and increased breast tissue susceptibility to hormonal changes. The role of prostaglandins and cytokines in mastalgia is being investigated. [10,11]

Mastalgia treatment involves a progressive approach, starting with conservative treatments and progressing to drug therapy as needed. This includes physical support, lifestyle changes, and over-the-counter medications. If symptoms persist, pharmaceutical measures may be considered. Evening primrose oil (EPO) is a common natural remedy, rich in omega-6 essential fatty acids, which can help control prostaglandin production and inflammatory responses in mastalgia patients. EPO is well-tolerated and has few adverse effects, but its efficacy is still under investigation. [12-14]

Ormeloxifene, a selective estrogen receptor modulator, is an effective mastalgia therapy due to its low side effects and cost. Studies show that it relieves symptoms and completely disappears fibroadenomas in 40% of women after three months. However, there is a lack of comparative research on the efficacy of diclofenac gel combined with ormeloxifene (EPO), highlighting the need for further research. [15,16] The study compares diclofenac gel plus ormeloxifene and evening primrose oil for treating mastalgia in benign breast disease, evaluating pain relief, patient satisfaction, and side effects.

Breast pain, a common symptom in benign breast diseases, is a significant issue affecting women, leading to physical discomfort and emotional distress. The management of mastalgia is challenging due to the lack of universally accepted standard therapies. Topical NSAIDs, hormonal modulators, and dietary supplements like evening primrose oil are used for treatment, but there is limited comparative data on their efficacy. This study to determine the effectiveness of diclofenac gel plus ormeloxifene and diclofenac gel plus evening primrose oil in treating mastalgia, guiding future clinical practice.

The study aims to compare diclofenac gel plus ormeloxifene and diclofenac gel plus evening primrose oil in treating mastalgia, focusing on the treatment response's effect on pain using visual analogue scale and pain chart.

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Methodology

Study design

Prospective comparative interventional study.

Study settings

Department of General Surgery at BRD Medical College, Gorakhpur, Uttar Pradesh, India. Duration - 12 months from December 2023 to December 2024, with patient enrollment occurring throughout.

Study Procedure

A detailed clinical history was taken for each patient, followed by a thorough clinical examination in the OPD. Relevant diagnostic assessments were conducted. Randomization was performed using a computer-generated random number table, and patients were assigned into two groups:

- **Group A:** Diclofenac gel + Ormeloxifene (30 mg twice a week for 3 months)
- **Group B:** Diclofenac gel + Evening Primrose Oil (1000 mg twice daily for 3 months)

Demographic variables, clinical history, general examination findings, and breast examination details were recorded on a pre-designed proforma. Patients were provided with a simple daily breast pain self-recording chart and were educated on its use. Patients with severe cyclical breast pain lasting more than 10 days per month were included. Informed written consent was obtained from all participants, ensuring confidentiality of patient credentials.

At the time of recruitment, a thorough history of the patient's illness was recorded. Patients were questioned regarding prior medical or alternative treatments attempted for their condition. Follow-ups were conducted at one month and three months, assessing objective and subjective symptom changes, with special attention to pain, which is the most significant symptom. Breast examinations were conducted at the first visit and repeated at one-month and three-month follow-ups. Examinations noted the size, site, number, consistency, and presence or absence of tenderness in breast lumps/masses. Patient compliance with treatment was assessed during each follow-up visit. At the end of treatment, participants were specifically asked about their experience with the treatment, its efficacy, and its impact on personal and social life.

Treatment response was assessed using the Visual Analogue Breast Pain Score.

Statistical analysis

Data were collected using a semi-structured questionnaire, and post-treatment complications were observed and recorded for up to 30 days after discharge.

Sample Size Calculation

The sample size was calculated using the formula: where:

- = required sample size,
- = 1.96 at 0.05 level of significance,
- = prevalence (47%) [26],
- = 10% margin of error.

Using these values, the calculated sample size was 96 patients. Considering a 10% non-response rate, the final sample size was rounded up to 100 patients

Sample size

Total 100 cases included in the study (50 in each group group)

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Inclusion Criteria

All female patients aged 18-45 years visiting the surgery department outpatient department (OPD) with complaints of mastalgia in benign breast diseases. Patients with written informed consent and women aged 18-45 with mastalgia and breast lump attending OPD at BRD Medical College, Gorakhpur were included.

Exclusion Criteria

Patients with malignancy, surgical candidates, renal or hepatic dysfunction, pregnant or lactating women, malabsorption syndrome, regular analgesics for unrelated conditions, and patients who refused consent.

Bias

Selection bias, Detection bias, Reporting bias

Ethical consideration

This study was approved by institutional human ethical committee BRD medical college Gorakhpur with approval no. 216/IHEC/2025.

Results

The study compared the age distribution of participants in two treatment groups: Ormeloxifene + Diclofenac Gel and Evening Primrose Oil + Diclofenac Gel. Out of 100 participants, 50 (50.0%) were assigned to the Ormeloxifene group and 50 (50.0%) to the Evening Primrose Oil group. The study compared the age distribution of participants in two treatment groups: Ormeloxifene and Evening Primrose Oil. Results showed similar socioeconomic status, religious distribution, and residence. Most participants were housewives, with a BMI of ≥25 kg/m², indicating overweight or obesity. Breast pain, lumpiness, menstrual cycle regularity, diabetes, hypertension, and thyroid disorders were similar between the two groups. No significant differences in comorbidities were found. The study analyzed substance use habits among participants in both treatment groups. Alcohol and tobacco use were absent in both groups, making statistical comparison unnecessary. Smokeless tobacco use was reported in 10% of participants in the Ormeloxifene group and 8% in the Evening Primrose Oil group, with no significant difference between the groups. (Table 1)

Table 1: Distribution of Study Participants in Demographic profile

	Ormeloxifene group (n=50)		**Evening Primrose Oil group (n=50)**		**Chi-sq.**	**p-value**
Age (yrs)	**N**	**%**	**N**	**%**		
18-24 years	17	34.00	25	50.00	5.98	0.201
25-29 years	10	20.00	4	8.00		
30-34 years	7	14.00	6	12.00		
35-39 years	8	16.00	4	8.00		
≥40 years	8	16.00	11	22.00		
Mean ± SD	29.36±7.96		28.60±9.68		p=0.669	
Socioeconomic status						
Lower	27	54.00	27	54.00	0.51	0.775
Lower Middle	17	34.00	19	38.00		

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Middle	6	12.00	4	8.00		
Religion						
Hindu	35	70.00	29	58.00	1.09	0.298
Muslim	15	30.00	21	42.00		
Marital status						
Marriage	32	64.00	24	48.00	1.99	0.259
Unmarried	18	36.00	26	52.00		
Occupation						
Employed	10	20.00	5	10.00	2.95	0.229
Housewife	23	46.00	21	42.00		
Student	17	34.00	24	48.00		
Residence						
Rural	38	76.00	41	82.00	0.24	0.623
Urban	12	24.00	9	18.00		
BMI (kg/m^2)						
<18 kg/m^2	3	6.00	3	6.00	0.25	0.969
18-22.9 kg/m^2	14	28.00	12	24.00		
23-24.9 kg.m^2	6	12.00	7	14.00		
≥25 kg/m^2	27	54.00	28	56.00		
Breast pain						
Yes	50	100.00	50	100.00	-	-
Lumpiness						
Yes	16	32.00	15	30.00	**0.05**	**0.829**
No	34	68.00	35	70.00		
Menstrual Cycle						
Irregular	11	22.00	12	24.00	0.06	0.812
Regular	39	78.00	38	76.00		
Alcohol						
No	50	100.00	50	100.00		
Tobacco						
No	50	100.00	50	100.00		
Smokeless tobacco						
Yes	5	10.00	4	8.00		**1.00**
No	45	90.00	46	92.00		

Table 2 shows high-resolution ultrasound (HR USG) findings among participants in both treatment groups. Bilateral fibrocystic changes were observed in 3 participants (6.00%) in the Ormeloxifene group and 4 participants (4.00%) in the Evening Primrose Oil group. Fibroadenoma with fibrocystic changes was detected in 3 participants (6.00%) in the Ormeloxifene group and 8.00% in the Evening Primrose Oil group. Isolated fibrocystic changes

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Original Article

were observed in 11 participants (22.0%) in the Ormeloxifene group and 18% in the Evening Primrose Oil group

Table 2: High-Resolution Ultrasound (HR USG) Findings among Study Participants

		Ormeloxifene group (n=50)		Evening Primrose Oil group (n=50)		Chi Sq.	p-Value
		n	%	n	%		
HR USG	B/Fibrocystic Changes	3	6.00	2	4.00	0.60	0.896
	Fibroadenoma With Fibrocystic Changes	3	6.00	4	8.00		
	Fibrocystic Changes	11	22.00	9	18.00		
	NAD	33	66.00	35	70.00		

The study analyzed the initial VAS scores of both the Ormeloxifene and Evening Primrose Oil treatment groups at baseline. Both groups had similar baseline pain levels. At one month, the VAS scores decreased in both groups, but the difference remained non-significant. At three months, the VAS scores continued to decrease significantly, but Ormeloxifene showed a greater reduction (1.36 ± 1.74) compared to the Evening Primrose Oil group (2.84 ± 2.05). This statistically significant difference suggests that Ormeloxifene was more effective in reducing pain at three months. Both treatments were effective in reducing pain over time, with intra-group p-values indicating that both treatments were effective. (Table 3)

Table 3: Comparison of VAS Scores at Different Time Points between the Two Treatment Groups

VAS score	Ormeloxifene group (n=50)		Evening Primrose Oil group (n=50)		t	p-Value
	N	%	N`	%		
At day 0	6.76	1.45	6.40	1.64	1.16	0.248
At 1 month	4.30	1.47	4.70	1.66	-1.28	0.205
At 3 Month	1.36	1.74	2.84	2.05	-3.89	<0.001
p-Value	<0.001		<0.001			

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Original Article

A study comparing Ormeloxifene and Evening Primrose Oil treatment outcomes found that Ormeloxifene showed a significantly higher improvement in mastalgia symptoms (76.00%) compared to Evening Primrose Oil (40.00%). Only 16.0% of participants in the Evening Primrose Oil group remained unimproved, while only 8.00% of the Ormeloxifene group and 20% of the Evening Primrose Oil group showed partial improvement. The Chi-square test showed a statistically significant difference, indicating Ormeloxifene + Diclofenac Gel was more effective in relieving mastalgia in benign breast disease. (Table 4)

Table 4: Treatment Outcome Comparison between Ormeloxifene and Evening Primrose Oil Groups

		Ormeloxifene group (n=50)		Evening Primrose Oil group (n=50)		Chi	p-Value
		N	%	N	%		
Outcome	Improved	38	76.00	20	40.00	13.30	0.001
	Not Improved	8	16.00	20	40.00		
	Partial Improved	4	8.00	10	20.00		

Discussion

The study found no significant age difference between Ormeloxifene and Evening Primrose Oil groups, with Ormeloxifene having 34.00% participants aged 18-24 and Evening Primrose Oil having 50.0%, with mean ages of 29.36 ± 7.96 years. Mastalgia primarily affects women in their twenties and early thirties, with no significant age-related differences in treatment response. Patients' average age is 21-30, with similar results for Ormeloxifene, Danazol, and Evening Primrose Oil. [17-25]

The study revealed that 54% of participants in both Ormeloxifene and Evening Primrose Oil groups were from lower socioeconomic status, with the middle-class category having the least representation. Mastalgia is more common among women from lower and lower-middle socioeconomic backgrounds, with limited access to specialized healthcare and financial constraints influencing treatment choices. Affordable treatments like Centchroman play a crucial role in treatment adherence among these groups. This finding supports previous studies indicating the need for accessible and affordable treatments to improve adherence and outcomes in mastalgia management. [17-25]

In our study we found no significant difference in religious distribution between the Ormeloxifene and Evening Primrose Oil groups, with Hindus comprising 70.00% and Muslims comprising 30.00%, as per a Chi-square test. Research shows that mastalgia affects women across religious groups without significant differences in treatment response. Hindu women are the majority of mastalgia cases, attributed to regional demographics and healthcare accessibility. However, cultural and religious factors have no significant influence on treatment choice or response. Both Hindu and Muslim women who have mastalgia feel better after treatment. Therefore, healthcare interventions should focus on accessibility and awareness to ensure appropriate care for all patients, regardless of religious background. [17-21]

The study found that 64% of participants in the Ormeloxifene group were married, while 48.0% were in the Evening Primrose Oil group. Both groups had housewives, students, and employed participants, with most living in rural areas. Research shows a higher prevalence of

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Original Article

mastalgia among married women, housewives, and students, with hormonal fluctuations and lifestyle factors contributing to the condition. Employment status doesn't significantly impact the prevalence, and most participants live in rural areas, indicating challenges in accessing healthcare. Rural areas often face barriers to accessing healthcare. [17-20,22,25]

The study found that 32% of participants in the Ormeloxifene group reported lumpiness, while 30.00% in the Evening Primrose Oil group did not, with no significant difference. Research shows that breast nodularity is a common symptom of mastalgia, with Ormeloxifene being the most effective in reducing symptoms. Studies have found that fibrocystic changes are common in people with mastalgia, and Ormeloxifene and Centchroman work better than Evening Primrose Oil at removing lumps. The study findings align with previous research, confirming that breast lumpiness is a common symptom. However, Ormeloxifene may help with long-term resolution more than Evening Primrose Oil. [17-22,25]

The study found that 22% of participants in the Ormeloxifene group had irregular menstrual cycles, while 78.00% had regular cycles. In the Evening Primrose Oil group, 24% had irregular cycles, but no significant difference was found. Previous research has explored the relationship between menstrual cycle regularity and mastalgia treatments. Research indicates that Ormeloxifene and Evening Primrose Oil do not significantly affect menstrual cycle regularity, while hormonal treatments like Tamoxifen and Danazol can influence patterns. Non-hormonal alternatives like Evening Primrose Oil have minimal effects on cycle regularity, indicating that hormonal treatments for mastalgia may influence menstrual patterns. [17-22,24]

The study found that most participants in both groups had a BMI of 25 kg/m² or higher, indicating overweight or obesity, with the normal range represented by 28.00% in the Ormeloxifene group and 24.00% in the Evening Primrose Oil group.

Research indicates a link between higher BMI and mastalgia, with a higher prevalence among overweight and obese women. However, studies have found no significant impact of BMI on treatment outcomes. Other studies suggest hormonal imbalances may cause breast pain. The study found that BMI did not significantly affect treatment response to Ormeloxifene or Evening Primrose Oil, suggesting that BMI does not affect the effectiveness of these treatments. [17-22,25]

The study found no significant difference in comorbidities between Ormeloxifene and Evening Primrose Oil groups, with diabetes, hypertension, and thyroid disorders present in 2.00% and 8.00% respectively.

Thyroid problems and metabolic conditions like diabetes and high blood pressure are often linked to mastalgia, but their presence doesn't significantly affect treatment effectiveness. Previous studies have found that women with pre-existing metabolic disturbances have a higher prevalence of mastalgia. However, these conditions do not significantly affect treatment outcomes. It's crucial to treat mastalgia in a way that considers both hormonal and metabolic factors, as these conditions are common comorbidities in mastalgia patients. [17-23,25]

The study revealed that fibrocystic structures were altered in 6.00% of participants in the Ormeloxifene group and 4.00% in the Evening Primrose Oil group, with fibroadenoma detected in 6.00% of the latter group. Studies have shown that fibrocystic changes and fibroadenomas are common in people with mastalgia. Ormeloxifene has been found to be the most effective treatment for reducing nodularity, with similar results from other studies. Studies have also found that anti-estrogen treatments work better than nutritional supplements like Evening Primrose Oil in resolving issues. The HR USG results for both treatment groups were similar, but Ormeloxifene may have a larger effect on nodularity over time. [17-25]

The study found that Ormeloxifene and Evening Primrose Oil treatments had similar pain levels at the start. After a

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month, both groups experienced a decrease in VAS scores, but the Ormeloxifene group showed better pain reduction. Both treatments were effective over time. Research shows that Ormeloxifene outperforms Evening Primrose Oil in reducing vasodilator-associated stress (VAS) scores at 12 weeks. Danazol has a stronger effect, while Ormeloxifene offers better pain relief. Centchroman (Ormeloxifene) helps with pain faster and longer than Evening Primrose Oil. Ormeloxifene is preferred due to its safety. Both Ormeloxifene and Evening Primrose Oil effectively reduce mastalgia-related pain, but Ormeloxifene reduces pain intensity by three months more than Evening Primrose Oil. [17-25]

The study found that Ormeloxifene significantly improved mastalgia symptoms in 76.00% of participants compared to 40.00% in the Evening Primrose Oil group, with only 16% remaining unimproved and 40.00% not improving. Ormeloxifene is a more effective treatment for mastalgia than Evening Primrose Oil and topical Diclofenac, according to studies by Trehan et al. (2024). Its efficacy is higher than Evening Primrose Oil, with 33.33% of patients responding to treatment. Ormeloxifene is also more effective than Danazol in reducing mastalgia symptoms, with the highest percentage of patients experiencing full symptom resolution. Research shows that Ormeloxifene works faster and more effectively than Evening Primrose Oil, making it a more reliable option for women experiencing persistent mastalgia. Hormonal modulators like Ormeloxifene and Tamoxifen are better at treating mastalgia over the long term than non-hormonal interventions like Evening Primrose Oil. [17-25]

Generalizability

- Prospective design and randomization
- Clear inclusion and exclusion criteria
- Standardized assessment VAS tool

Limitations

The study has limitations, including a small sample size, a three-month follow-up period, insufficient analysis of factors like dietary habits, stress, and hormonal variations, and self-reported patient adherence to treatment. Future studies with larger populations and longer follow-ups are needed to validate findings and assess long-term outcomes.

Recommendation

The study suggests using Diclofenac gel combined with Ormeloxifene or Evening Primrose Oil for managing mastalgia in benign breast diseases. It recommends individualized treatment based on symptom severity, patient preference, and tolerance. Regular follow-up is recommended for pain relief, adherence, and side effects. Further large-scale studies are needed for validation and standardized treatment protocols.

Conclusion

The study found that Ormeloxifene is more effective than Evening Primrose Oil in managing mastalgia. Over time, both treatments reduced pain, but Ormeloxifene had a larger effect on VAS scores by three months, indicating its more effective pain management. Furthermore, 76.00% of participants in the Ormeloxifene group showed improvements compared to 40.00% in the Evening Primrose Oil group. Both groups had similar baseline characteristics, comorbidities, and menstrual cycle regularity. The results align with previous studies that found Ormeloxifene more effective than Evening Primrose Oil and other non-hormonal treatments. Evening Primrose Oil, despite its safety, has limited effectiveness compared to hormonal modulators like Ormeloxifene. Future research with larger sample sizes and longer follow-up periods may further establish Ormeloxifene long-term benefits and safety profile.

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Conflict of interest

No conflict of interest

Availability of data

No

Authors contribution.

Dr. Upendra Yadav (Resident): Patients enrolment, data collection Analysis, Patient treatment.
Dr. Ashok Kumar (MS, FLCS, FAIS Professor and HOD): Concept and design of study
Dr. Deepak Singh (MS, Assistant professor): Supervision and formal analysis of surgery
Dr. Aquil Ahmad (MS Assistant professor): Layout of study and writing
Dr. Ujjwal Awasthi (Resident): Analysis of study

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Original Article

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