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Original Research Article

A Study of Efficacy of Ormeloxiffine and Evening Primrose Oil in Treatment of Mastalgia: A Randomised Control Study

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Conflict of interest: Nil

Abstract:

Objective: The present study was to compare the efficacy and severity of Ormeloxifene and Evening Primrose Oil in the management of mastalgia.

Methods: Women aged 18 to 50 years with complaints of breast pain (mastalgia) were included. A total of 100 eligible female patients were enrolled and randomized into two groups: Group A (n=50): Received Ormeloxifene 30 mg, twice weekly for 12 weeks. Group B (n=50): Received Evening Primrose Oil 1000 mg, once daily for 12 weeks. severity of mastalgia was assessed by visual analogue scale (VAS) score ranging from 0-10, zero (0) indicating no pain and ten (10) indicating severe pain.

Results: At each time interval (12, 16, 20, and 24 weeks), Group A demonstrates a significantly greater reduction in pain compared to Group B. The mean change in pain for Group A is consistently higher across all time points, with p-values less than 0.001 for each comparison, indicating statistically significant differences in pain reduction between the two groups.

Conclusion: Ormeloxifene is a novel non-steroidal, selective antiestrogen and can be used for the treatment of the benign breast diseases, mastalgia, nodularity, and small fibroadenomas.

Keywords: Mastalgia, Ormeloxifene, Evening Primrose Oil, VAS.

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Introduction

Mastalgia, or breast pain, is among the most common complaints encountered in breast clinics, affecting up to 70% of women at some point in their lives. Though often benign, it can cause significant anxiety due to fear of breast cancer and can interfere with daily, professional, and social functioning. Clinically, mastalgia is categorized into two main types—cyclical and non-cyclical—based on its relationship with the menstrual cycle. While cyclical mastalgia is hormonally influenced and often self-limiting, non-cyclical mastalgia may be more persistent and difficult to treat [1].

Multiple treatment options are available for mastalgia, ranging from reassurance and lifestyle modifications to pharmacological interventions. Among the pharmacological agents, Evening Primrose Oil (EPO)—a source of gamma-linolenic acid—is widely used due to its safety profile, though its efficacy remains controversial. On the other hand, Ormeloxifene, a selective estrogen receptor modulator originally developed as a contraceptive, has emerged as a promising agent for mastalgia, demonstrating both efficacy and minimal side effects in other studies [2].

Despite widespread use of both agents, there is limited comparative data on their relative effectiveness. Objective of the present study was to compare the efficacy of Ormeloxifene and Evening Primrose Oil in the management of mastalgia and assess the severity of mastalgia by visual analogue scale (VAS) score ranging from 0-10, zero (0) indicating no pain and ten (10) indicating severe pain.

Materials and Methods

The present study was conducted at the Department of General Surgery, Kalinga Institute of Medical Sciences (KIMS), Bhubaneswar during a period from February 2023 to January 2025.

Entire subjects signed an informed consent approved institutional ethical committee of Kalinga Institute of Medical Sciences (KIMS), Bhubaneswar was sought.

Study Design: The study followed CONSORT guidelines for randomized trials.

Sample Size Calculation: The sample size was calculated based on a prior study by Ahluwalia et al. (2021), where the mean VAS score at 24 weeks for Centchroman and Evening Primrose Oil was 0.43 (±0.90) and 1.18 (±1.0) respectively. Using a 95% confidence interval, 95% power, and a significance level of 5%, the minimum sample size was calculated as 86 participants (43 per group). Considering a 15% dropout rate, the final sample size was fixed at 100, with 50 participants in each group.

Study Population: Women aged 18 to 50 years presenting to the surgical outpatient department with complaints of breast pain (mastalgia) were considered for inclusion. A total of 100 eligible female patients were enrolled and randomized into two groups:

- Group A (n=50): Received Ormeloxifene 30 mg, twice weekly for 12 weeks.
- Group B (n=50): Received Evening Primrose Oil 1000 mg, once daily for 12 weeks.

Inclusion Criteria:

- Females aged between 18 and 50 years.
- Presenting with cyclical or non-cyclical mastalgia.
- Willing to give written informed consent.
- No detectable mass suggestive of malignancy on clinical or radiological evaluation.

Exclusion Criteria:

- **For Ormeloxifene Group:**
    - History of breast cancer or strong family history.
    - Women in the first 6 months postpartum or breastfeeding.
    - Pregnant or planning pregnancy.
    - Recent jaundice, hepatic or renal impairment, active tuberculosis.
    - Known allergic conditions.
    - Patients with discrete and dominant lump which is suspicious of cancer
- **For Evening Primrose Oil Group:**
- History of epilepsy or seizure disorders.

Methods

Patients were interviewed and full history including the pain, lump, nipple discharge and demographic data was recorded. Thorough clinical examination of breast and axilla was done. All routine investigations were done including USG breast for patients < 40 years and mammogram for patients > 40 years in this study. Benign breast disease with mastalgia was identified, conservative management was done. Patients outcome for treatment was documented. The entire data was recorded in individual patient's proforma.

Clinical Assessment: Baseline data including age, menstrual history, parity, age at menarche and first pregnancy, body mass index (BMI), comorbidities, and type and duration of mastalgia were recorded. A thorough clinical breast examination, along with ultrasound (for <40 years) or mammography (for ≥40 years), was performed to rule out any suspicious masses.

Outcome Measures:

- **Primary Outcome:** Reduction in VAS (Visual Analogue Scale) score from baseline to 24 weeks.
- **Secondary Outcomes:** Mean change in pain over follow-up, recurrence of mastalgia, need for escalation to Danazol therapy, and any reported side effects.

Follow-Up Protocol: Participants were assessed at baseline, 12, 16, 20, and 24 weeks. Pain scores were recorded using the VAS scale (0–10) at each visit. Compliance and side effects were also monitored. After 12 weeks of intervention, patients were followed up without medication to assess for sustained response or recurrence of mastalgia.

Method of follow-up: Follow- up till 24 weeks was done without medication to assess sustained response or recurrence of mastalgia.

Statistical Analysis

Data was analyzed by using IBM SPSS (Version 26.0) software. Mean ± SD were observed. Student T-Test or Mann Whitney Test were applied. P-value was taken less than or equal to 0.05 ($p \leq 0.05$) for significant differences.

Results

Table 1: Age Group

Age Group	Group A (Ormeloxifene)	Group B (Evening Primrose Oil)	Total
21 – 30	11	13	24
31 – 40	13	22	35
41 – 50	26	15	41
Total	50	50	100

p-value = 0.14

In Group A, the majorities of participants fall in the 41-50 age range (26 participants), while Group B has the highest concentration in the 31-40 age range (22 participants).

Table 2: showing the Comorbidity

Comorbidity	Group A (Ormeloxifene)	Group B (Evening Primrose Oil)
BA	0	1
COPD, HTN	1	0
DM	4	4
DM, HTN, CAD	2	3
DM, Hypothyroid	0	1
HTN	3	3
Nil	40	38
Total	50	50

p-value = 0.87

The majorities of participants in both groups have no comorbidities, with 40 individuals in Group A and 38 in Group B. The table also highlights specific comorbidities such as Diabetes Mellitus (DM), Hypertension (HTN), Chronic Obstructive Pulmonary Disease (COPD), and others, with no significant differences between the groups, as indicated by a p-value of 0.87.

The majorities of participants in both groups have the left breast involved, with 31 participants in Group A and 28 in Group B, totaling 59 individuals. The right breast is involved in 19 participants from Group A and 22 from Group B, totaling 41 participants. The p-value of 0.54 indicates no significant difference between the two groups in terms of the side of the breast affected.

The majorities of participants in both groups experienced menarche before the age of 12, with 36 participants in Group A and 33 in Group B, totaling 69 individuals. A smaller number of participants had menarche between the ages of 13-14 (23 participants total) or after the age of 14 (8 participants total). The p-value of 0.71 suggests no significant difference between the two groups regarding the age at menarche.

The majorities of participants in both groups had their first pregnancy between the ages of 18-20, with 32 participants in Group A and 34 in Group B, totaling 66 individuals. Fewer participants had their first pregnancy between the ages of 21-25 (18 participants total) or after the age of 25 (16 participants total). The p-value of 0.87 indicates no significant difference between the two groups in terms of the age at first pregnancy.

A large majority of participants in both groups have a BMI greater than 25, with 40 participants in Group A and 42 in Group B, totaling 82 individuals. Only 18 participants (10 in Group A and 8 in Group B) have a BMI of less than 25. The p-value of 0.60 suggests no significant difference between the two groups in terms of BMI distribution.

Table 3: Type of Mastalgia

Type of Mastalgia	Group A (Ormeloxifene)	Group B (Evening Primrose Oil)	Total
Cyclical	17	17	34
Non-Cyclical	33	33	66
Total	50	50	100

p-value = 1.00

The majorities of participants in both groups experience non-cyclical mastalgia, with 33 individuals in each group, totaling 66 participants. A smaller number of participants have cyclical mastalgia, with 17 individuals in each group, totaling 34 participants. The p-value of 1.00 indicates no significant difference between the two groups in the type of mastalgia experienced.

At the baseline (0 weeks), the VAS scores are similar between the two groups, with Group A at 6.94 ± 1.61 and Group B at 6.66 ± 1.63 (p-value = 0.39). However, significant differences emerge at

subsequent time points, with Group A showing greater reductions in VAS scores at 12, 16, 20, and 24 weeks compared to Group B. The p-values for these time points are all less than 0.05, indicating statistically significant differences, especially at 12, 16, and 20 weeks, where p-values are below 0.001.

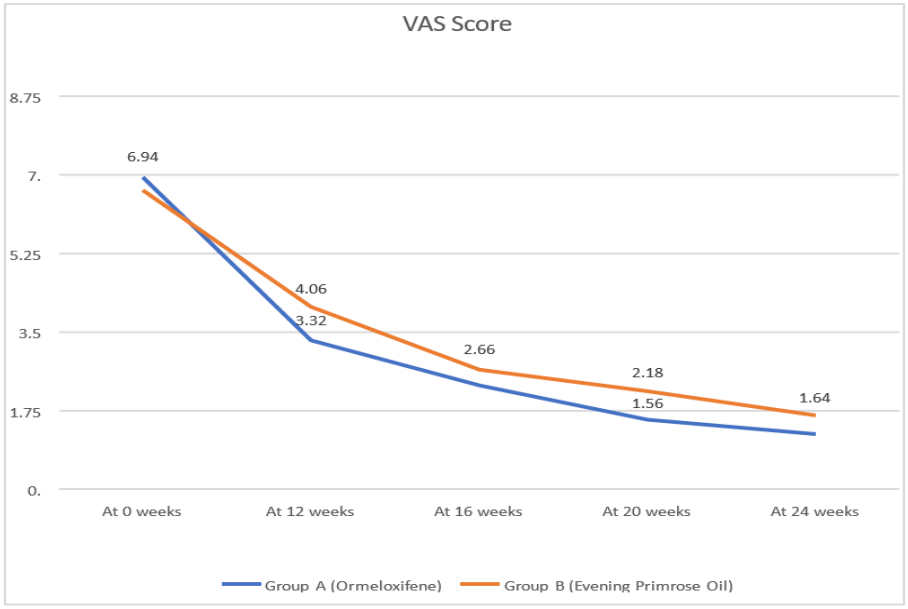

Figure 1: Comparison of mean of VAS score between two groups.

At each time interval (12, 16, 20, and 24 weeks), Group A demonstrates a significantly greater reduction in pain compared to Group B. The mean change in pain for Group A is consistently higher across all time points, with p-values less than 0.001 for each comparison, indicating statistically significant differences in pain reduction between the two groups.

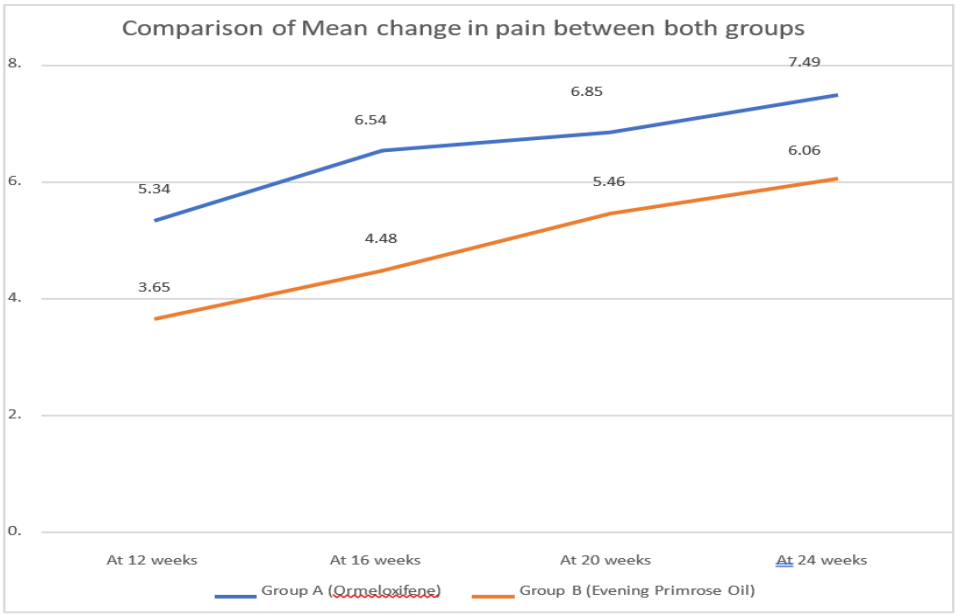

Figure 2: Comparison of Mean change in pain between both groups

Table 4: Shift to Danazol

Shifted to Surgery	Group A (Ormeloxifene)	Group B (Evening Primrose Oil)	Total
Not Shifted	48	41	89
Shifted	2	9	11
Total	50	50	100

p-value = 0.04

The majorities of participants in both groups did not shift to Danazol, with 48 participants in Group A and 41 in Group B, totaling 89 individuals. However, a higher proportion of participants in Group B shifted to Danazol (9 participants) compared to Group A (2 participants). The p-value of 0.04 indicates a statistically significant difference between the two groups in terms of the shift to Danazol treatment.

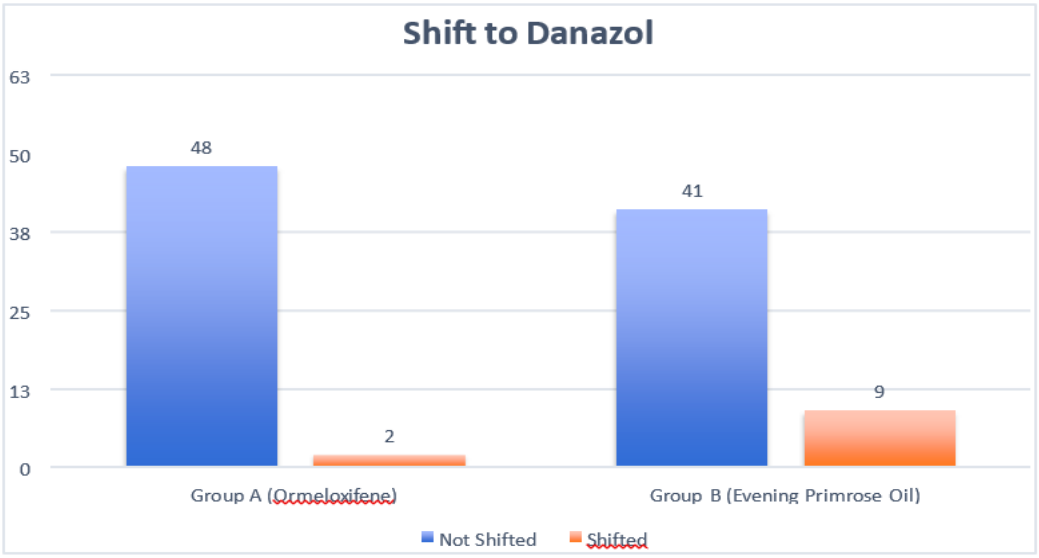

Figure.4: Shift to Danazol

Discussion

The most prevalent breast symptom among patients who visit a breast clinic is mastalgia. Between 60 and 70 percent of women have some form of breast pain throughout their lives, with 10–20% of them experiencing severe pain. Fear of breast cancer and the existence of excruciating pain that lowers quality of life are the two most frequent worries of patients who present with mastalgia. Simple medications and reassurance can be used to treat most mastalgia patients. Breast nodules that are painful or lack a noticeable lump are frequently linked to mastalgia. Normal people experience some degree of mastalgia and breast nodularity.

The origin and best course of treatment for mastalgia, a prevalent and mysterious ailment, are still not well understood. Mastalgia's impact on quality of life is frequently underestimated, and it can be severe enough to disrupt regular daily activities. Most patients can achieve positive results with reassurance, nonpharmacological interventions, and in certain cases, one of several useful drugs. A more recent medication called ormeloxifene has demonstrated encouraging outcomes with few adverse effects when used to treat mastalgia and lower the morbidity of surgery. In order to determine the effects of ormeloxifene against evening primrose oil, which is frequently utilized in our hospital, we are conducting a comparative study. In order to compare the effectiveness of ormeloxifene and evening primrose oil in treating mastalgia, this study was carried out.

A total of 100 patients were recruited for the study, 50 patients in each Ormeloxifene group and Evening Primrose Oil group. The majority of the patients in ormeloxifene group are between 41-50 age range (26 participants), while in Evening primerose oil group the majority are between 31-40 age range. 280 patients were enrolled in the Banerjee et al. study [3]. One hundred patients in the Evening Primerose Oil and Ormeloxifne Group were between the ages of 20 and 35, and forty patients in each group were between the ages of 35 and 50 [3]. However, our investigation revealed that, in contrast to Banerjee et al.'s study, the majority of patients in the ormeloxifene group (26 participants) are between the ages of 41 and 50, whereas the majority in the evening primerose oil group are between the ages of 31 and 40.

According to Nigam et al., 90 patients in all were involved. For mastalgia, 45 patients received evening primrose oil, while 45 patients received ormeloxifene. 40 patients, or the maximum number of participants, were in the age range of 21 to 30[47]. All participants were 31 ± 8.42 years old on average [4]. Our study revealed that, in contrast to Nigam et al.'s, the majority of patients in the ormeloxifene group (26 participants) are between the ages of 41 and 50, whereas the majority in the evening primerose oil group are between the ages of 31 and 40.

The majorities of participants in both groups have no comorbidities, with 40 individuals in Group A and 38 in Group B.

A large majority of participants in both groups have a BMI greater than 25, with 40 participants in ormeloxifene group and 42 in Evening primerose oil group, totaling 82 individuals. Only 18 participants (10 in Group A and 8 in Group B) have a BMI of less than 25.

We assessed the side of breast involvement, the majority of participants in both groups have the left breast involved, with 31 patients in ormeloxifene group and 28 in Evening primerose oil group, totaling 59 individuals. The right breast is involved in 19 participants from Group A and 22 from Group B, totaling 41 participants.

The majority of participants in both groups attained menarche before the age of 12. Under 12 36 patients in oremeloxifene group attained menarche and 33 patients in Evening primerose oil group attained menarche. A Minority of patients had menarche between the ages of 13- 14 (23 participants total) or after the age of 14 (8 participants total).

The majorities of participants in both groups had their first pregnancy between the ages of 18-20, with 32 members in ormeloxifene group and 34 in Evening primerose oil group, totaling 66 individuals. Fewer participants had their first pregnancy between the ages of 21-25 (18 participants total) or after the age of 25 (16 participants total).

The majorities of participants in both groups experience non-cyclical mastalgia, with 33 individuals in each group, totaling 66 participants. A smaller number of participants have cyclical mastalgia, with 17 individuals in each group, totaling 34 participants. Of the patients, 22.3% had non-cyclical mastalgia and 77.7% had cyclical mastalgia, according to Nigam et al., [4]. The majority of participants in both groups—33 in each group, for a total of 66 participants—experience non-cyclical mastalgia, according to our study, which differs from that of Nigam et al. [4]. Of the 34 participants, 17 in each group have cyclical mastalgia, which is a decreased percentage. Breast pain charts have been used to determine if mastalgia is cyclical or non-cyclical in nature and to choose the best course of treatment. Patients are requested to record their menstrual cycle and breast pain every day for two months.

We compared the VAS scores between the both groups. At the baseline (0 weeks), the VAS scores are similar between the two groups, with Group A at 6.94 ± 1.61 and Group B at 6.66 ± 1.63 (p-value = 0.39). However, significant differences emerge at subsequent time points, with Ormeloxifene group showing greater reductions in VAS scores at 12, 16, 20, and 24 weeks compared to Evening primerose oil group. The p-values for these time points are all less than 0.05, indicating statistically significant differences, especially at 12, 16, and 20 weeks, where p- values are below 0.001.

At each time interval (12, 16, 20, and 24 weeks), Ormeloxifene group demonstrates a significantly greater reduction in pain compared to Evening primerose oil group. The mean change in pain for ormeloxifne is consistently higher across all time points, with p-values less than 0.001 for each comparison, indicating statistically significant differences in pain reduction between the two groups.

According to a study by Banerjee et al., patients in Group A (Ormeloxifene) had a mean VAS score of 5.71 at the beginning of treatment, but patients in Group B had a mean VAS score of 5.6. At the conclusion of the first month following the start of treatment, Group A reported a mean VAS score of 4.00, indicating a considerable reduction in mastalgia, while Group B recorded a score of 4.90. Group B showed a gradual decline, with a mean VAS score of 4.50 at the conclusion of the sixth month. Group A experienced a notable decline, with a negligible mean VAS score of 0.80 at the end of the sixth month [48]. Similar to Banerjee et al., study, our study also showed significant reduction in vas scores of ormeloxifene group (At 12 weeks 3.32 ± 1.22 vs 4.06 ± 1.36, At 16 weeks 2.32 ± 1.48vs 2.66 ± 1.35, At 20 weeks vs 1.56 ± 0.99 2.18 ± 1.29, At 24 weeks 1.24 ± 1.15 vs 1.64 ± 1.44).

According to Nigam et al., [47] patients' VAS scores ranged from three to seven at the time of presentation. The highest number of participants—34, or 37.8%—had a VAS base score of 5. Overall, 54 participants (60%) had a VAS score of 0 at the end of the first month. Following the first month, there was a statistically significant difference ($p<0.05$) in the VAS scores of groups A and B. The VAS base score of B was clearly visible, with a mean difference of 1.64 and a confidence interval of 1.07 to 2.21. It suggested that ormeloxifene tablets were superior to evening primrose oil tablets after a month, as group A's mean score was higher than group B's VAS base score. Following the second month, there was a statistically significant difference in the VAS base score between groups A and B ($p =.000 <.05$). With a mean difference of 1.18 and a confidence interval of.71.1.64, group A's VAS base score was higher than group B's, demonstrating once more that ormeloxifene was more effective than evening primrose oil at the time. Following the second month, there was a statistically significant difference in the VAS base score between groups A and B ($p =.000 <.05$). With a mean difference of 1.18 and a confidence interval of.71.1.64, group A's VAS base score was higher than group B's, demonstrating once more that ormeloxifene was more effective than evening primrose oil at the time. Following the first, second, and third months, there is consistently a statistically significant difference between group A

and group B VAS ratings (p =.000 <.05). All things considered, ormeloxifene is better or more efficient than evening primrose oil [4]. His results are in line with our study.

The majority of participants in both groups did not shift to Danazol, with 48 participants in Group A and 41 in Group B, totaling 89 individuals. However, a higher proportion of participants in Group B shifted to Danazol (9 participants) compared to Group A (2 participants).

In a 2013 comprehensive review of the knowledge and treatment of mastalgia, Kataria et al. found that antiestrogen medication (centchroman) was superior to evening primrose oil in terms of efficacy [5]. In 2004, Uma et al. observed that in a small group of patients with refractory mastalgia, dietary changes combined with reassurance proved to be effective in over 94% of cases [6].

Janaki et al., demonstrated in a sizable (n=1000) observational study conducted in Pondicherry, India, that clinical breast examination remains the gold standard and is more effective when combined with USG and FNAC, while self-breast inspection is little understood [7]. Omega-6 essential fatty acids are abundant in evening primrose oil (Oenothera biennis), which is made from evening primrose seeds. It is frequently employed as a substitute treatment for mastalgia. Despite being well tolerated, the majority of trials have produced less than ideal results, according to Bayles and Usatine [8].

According to Dhar et al., 90% of patients taking ormeloxifene saw a drop in their VAS score from 10 to 3 at the end of the first week, and 100% of patients had a VAS score of 0 by the end of the first month [9]. According to Tejwani et al., using ormeloxifene for six months increased the likelihood of staying pain-free by 71% [10]. In their 2013 study, S Kumar et al. examined the impact of ormeloxifene on mastalgia and discovered that the active group's mean pain level considerably decreased in comparison to the placebo group's ($F = 18.66$, $p < 0.0001$), with a systematic downward trend over three months ($F = 105.23$, $p < 0.0001$) [11].

Rajswaroob et al. found that 13 patients had a VAS score of 2 and 31 patients had a score of 0 following three months of ormeloxifene treatment [12]. According to Rathi J et al., patients taking ormeloxifene experienced a significant decrease in their median pain score over the course of multiple visits ($p = 0.001$). A higher percentage of women in the ormeloxifene group report living pain-free lives even after taking the medication, which may indicate a longer-lasting impact [13]. According to Thakur et al., 87% of women experienced a decrease in pain score < 3 after taking ormeloxifene for 12 weeks [14]. The mean pain level steadily dropped over the course of three months (5.8 to 0.86), according to a recent study conducted in August 2017 by Gandhi et al. [15].

Limitations

The primary limitation our study is single center study. The second limitations in less sample size, thus, a multicentered trial with a large sample size is required in the future. The third limitations we have not compared the USG findings in between the groups.

Summary

- A total of 100 patients were recruited for the study, 50 patients in each Ormeloxifene group and Evening Primrose Oil group. The majority of the patients in ormeloxifene group are between 41-50 age range (26 participants), while in Evening primerose oil group the majority are between 31-40 age range.
- The majority of participants in both groups have no comorbidities, with 40 individuals in Group A and 38 in Group B.
- A large majority of participants in both groups have a BMI greater than 25, with 40 participants in ormelodifene group and 42 in Evening primerose oil group, totaling 82 individuals. Only 18 participants (10 in Group A and 8 in Group B) have a BMI of less than 25.
- We assessed the side of breast involvement, the majority of participants in both groups have the left breast involved, with 31 patients in ormeloxifene group and 28 in Evening primerose oil group, totaling 59 individuals. The right breast is involved in 19 participants from Group A and 22 from Group B, totaling 41 participants.
- The majority of participants in both groups attained menarche before the age of 12. Under 12 36 patients in oremeloxifene group attained menarche and 33 patients in Evening primerose oil group attained menarche. A Minority of patients had menarche between the ages of 13-14 (23 participants total) or after the age of 14 (8 participants total).
- The majority of participants in both groups had their first pregnancy between the ages of 18-20, with 32 members in ormeloxifene group and 34 in Evening primerose oil group, totaling 66 individuals. Fewer participants had their first pregnancy between the ages of 21-25 (18 participants total) or after the age of 25 (16 participants total).
- The majority of participants in both groups experience non-cyclical mastalgia, with 33 individuals in each group, totaling 66 participants. A smaller number of participants have cyclical mastalgia, with 17 individuals in each group, totaling 34 participants.

- We compared the VAS scores between the both groups. At the baseline (0 weeks), the VAS scores are similar between the two groups, with Group A at 6.94 ± 1.61 and Group B at 6.66 ± 1.63 (p-value = 0.39). However, significant differences emerge at subsequent time points, with Ormeloxifene group showing greater reductions in VAS scores at 12, 16, 20, and 24 weeks compared to Evening primerose oil group. The p-values for these time points are all less than 0.05, indicating statistically significant differences, especially at 12, 16, and 20 weeks, where p- values are below 0.001.
- At each time interval (12, 16, 20, and 24 weeks), Ormeloxifene group demonstrates a significantly greater reduction in pain compared to Evening primerose oil group. The mean change in pain for ormeloxifne is consistently higher across all time points, with p-values less than 0.001 for each comparison, indicating statistically significant differences in pain reduction between the two groups.
- The majorities of participants in both groups did not shift to Danazol, with 48 participants in Group A and 41 in Group B, totaling 89 individuals. However, a higher proportion of participants in Group B shifted to Danazol (9 participants) compared to Group A (2 participants).

Conclusion

The present study concluded that the non-cyclical mastalgia are more common as compared to cyclical mastalgia. Mean change in pain with ormeloxifne is consistently higher as compared to evening primrose oil. Hence, Ormeloxifene is a novel non-steroidal, selective antiestrogen and can be used in future for treatment of the benign breast diseases, mastalgia, nodularity, and small fibroadenomas.

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