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EFFECT OF ORMELOXIFENE (CENTCHROMAN) ON MASTALGIA AND MULTIPLE FIBROADENOMA

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Abstract

Introduction: Both mastalgia and fibroadenomas are the most prevalent benign breast disorders that present in breast clinics, and both create a great deal of concern in their patients. Hormonal medication treatments, among other forms of treatment, are becoming more and more common. An antiestrogenic medication called ormeloxifene (centchroman) has been demonstrated to lessen fibroadenoma size and to lessen discomfort in people with mastalgia.

Objectives: Ormeloxifene is a nonsteroidal medication that selectively inhibits estrogen. Because of its distinctive antiestrogen activity, it can be used to treat many tiny fibroadenomas and mastalgia. This study aimed to assess the effects of ormeloxifene (centchroman) and mastalgia on multiple fibroadenomas.

Materials and Methods: Among them were patients with benign breast disease who visited our outpatient surgery department between May 2023 and December 2023. For three months, they received Ormeloxifene 30 mg on alternate days, and they underwent follow-up care for six months. The Visual Analog Scale (VAS) for pain and ultrasonography (USG) for breast lump size were among the parameters that were recorded.

Results: The investigation involved sixty patients. Thirty patients were administered Ormeloxifene and thirty patients were administered other drugs. In mastalgia, we had a very good response; 90% of patients had a reduction in VAS scores from 7 to 3 within the first week, and nearly all were pain-free after a month. According to the final result, patients who received ormeloxifene had completely resolved the lump in 3.33% of cases by the end of three months and 30% by the end of six months. Partial or no response was found in 20% of the patients by 3rd month and 46.67% of the patients who were administered Ormeloxifene.

Conclusion: For the treatment of fibroadenoma and mastalgia, ormeloxifene has been shown to be a safe medication. In the group with mastalgia, its findings were very noteworthy. After six months, there had been fewer procedures and a significant increase in patient satisfaction.

Keywords: Breast lump, multiple fibroadenoma, centchroman, mastalgia, ormeloxifene

INTRODUCTION

In breast clinics, lumps and pain are frequent complaints, and over 90% of these cases are benign. Fibroadenomas are the most prevalent benign breast lumps in teenagers, typically affecting those under 30. In 20% of cases, they can show as more than one mass, but they usually present as a single mass. Numerous fibroadenomas in women are frequently inherited. Although the exact cause of numerous fibroadenomas is unknown, potential causes include the use of oral contraceptive pills (OCPs), an

imbalance between prolactin and estrogen levels, a reaction of the local breast tissue to estrogen, and a genetic or nutritional predisposition.

In one breast of a woman of reproductive age, multiple fibroadenomas are described as having three or more fibroadenomas. Symptomatic fibroadenomas larger than 4 cm, enlarging quickly, or resulting in cosmetic breast deformity typically necessitate surgical treatment. However, because numerous fibroadenomas are uncommon and there is a dearth of original research, managing and treating them can be difficult. Surgical treatments frequently cause psychological stress, breast deformity, and scarring. Although they are more costly, minimally invasive techniques including radiofrequency ablation and vacuum-assisted breast biopsies are recommended.

An alternate treatment for fibroadenomas is hormone therapy using antiestrogenic medications since fibroadenomas are thought to be caused by lobular tissue that is overly receptive to estrogen. Nonhormonal antiestrogenic medications such as Tamoxifen and Ormeloxifene are examples of selective estrogen receptor modulators (SERMs). Ormeloxifene exhibits a mild agonistic impact on the endometrium and a substantial antagonistic effect on the breast ductolobular epithelium. Under the trade name Saheli, it has been sold as a birth control pill in India since the 1990s. Comparing this medication to tamoxifen, the safety profile is superior and the adverse effects are far less severe.

Mastalgia, or breast pain, can be cyclical or non-cyclical and may cause significant anxiety and interference in daily life. Hormonal management agents like Tamoxifen, Danazol, Bromocriptine, and LH-RH analogues are commonly used for mastalgia. Ormeloxifene, a non-steroidal selective antiestrogen (SERM), is being explored as a treatment option.

MATERIALS AND METHODS

Patients ≤35 years old who visited the breast clinic for mastalgia or fibroadenoma were included in this study. Individuals with fibroadenomas larger than 5 cm and polycystic ovarian disease were not accepted. Detailed histories, demographic profiles, and clinical aspects were documented after obtaining signed consent. For 12 weeks, patients were provided 30mg of Centchroman on alternate days, and they were checked on at 3 & 6 months. The clinical examination, the VAS for discomfort, and USG for the size of the breast lump were used to evaluate the response to therapy. The volume of the lump had been computed employing the following formula: volume (cm^3)=(a × b × c × 0.52), where an is the biggest dimension, b is the dimension perpendicular to a, & c is equal to abs/2. In the statistical research, which employed mean and SD, percentage, and paired t-test, $P<0.05$ was considered significant.

RESULTS

Sixty individuals (≥3) with numerous fibroadenomas were included in the study. Positive family history was discovered in 20% of cases, with the age group of 21–25 years having the highest occurrence. 23.3% of patients had used oral contraceptives in the past. There was a higher incidence in the body mass index (BMI) group of 19–21kg/m^2, with an average BMI of 19.5kg/m^2.

Within the first week, 90% of patients had a decrease in their VAS scores from 7 to 3, and by the end of the month, nearly all had no pain.

Response to Ormeloxifene therapy was evaluated at 3 and 6 months.

The final response showed complete dissolution of the lump in 3.33% of the patients by three months and 30% by the end of 6th month in patients who were administered Ormeloxifene. Partial or no response was found in 20% of the patients by 3rd month and 46.67% of the patients who were administered Ormeloxifene.

RESPONSE	3RD MONTH	6TH MONTH	OVERALL RESPONSE	3RD MONTH	6TH MONTH	OVERALL RESPONSE
COMPLETE DISSOLUTION	1 (3.33)	9 (30)	10 (33.33)	0 (0)	3(10)	3 (10)
PARTIAL RESPONSE (50% DECREASE IN SIZE CLINICALLY AND RADIOLOGICALLY), NO RESPONSE OR INCREASE IN SIZE	6 (20)	14 (46.67)	20 (66.67)	11 (36.67)	16 (53.33))	27(90)
TOTAL	7	23	30	11	19	30

DISCUSSION

One of the most prevalent benign breast lumps, especially in young women, is fibroadenomas. When symptomatic, they usually necessitate surgery and might be single or many. Hormonal therapy is a non-surgical alternative, and Ormeloxifene has shown promise in reducing fibroadenoma size and alleviating mastalgia.

This study showed significant improvement in mastalgia symptoms with Ormeloxifene, as evidenced by the reduction in VAS scores. Additionally, there was a noticeable reduction in the size of fibroadenomas, with complete or partial response in the majority of cases. According to these results, ormeloxifene is a safe and effective therapy option for fibroadenomas and mastalgia that may lessen the need for surgery and increase patient satisfaction.

CONCLUSION

Ormeloxifene has proven to be an effective and safe treatment for mastalgia and multiple fibroadenomas. The significant reduction in pain and fibroadenoma size observed in this study supports its use as a non-surgical treatment option, leading to fewer surgeries and greater patient satisfaction. It is advised that these findings be further validated by bigger sample numbers and longer follow-up periods in future research.

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