

Efficacy of centchroman in treating mastalgia and fibroadenoma: A comprehensive institutional analysis



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ABSTRACT

Background: Mastalgia and fibroadenoma are common in women under 35. The management of these conditions is not standardized, and most treatments are costly with side effects. **Aims and Objectives:** The study aimed to assess the effect of ormeloxifene (Centchroman), a selective estrogen receptor modulator, on mastalgia and fibroadenoma. **Materials and Methods:** Women aged 35 and under with benign breast disease sought treatment at a surgery outpatient department from October 2023 to September 2024. They were given a regimen of 30 mg of Centchroman every other day for 12 weeks. Follow-up evaluations occurred at weeks 4, 8, 12, and 24 to track their progress. Results were meticulously assessed through clinical examinations, ultrasound measurements of breast lump size, and pain evaluations using a Visual Analog Scale (VAS). This approach ensures comprehensive care and monitoring for optimal outcomes. **Results:** A total of 104 patients were included of which 70 with mastalgia, 34 with fibroadenoma with symptom of pain (non-cyclical in 52 patients and cyclical in 18). Severe pain with VAS score of 10 in 50 patients was noted. Patients with fibroadenoma ranged from 1.5 to 5 cm with either single or multiple in one or both breasts. About 67.14% of patients saw a significant pain reduction from VAS score 10 to 3 in the 1st month. Almost all were painless at 3 months with nodularity disappearance. Mastalgia in fibroadenoma showed mixed response with complete disappearance in 32.35%, partial regression in 47.05%, and no response in 20.59%. **Conclusion:** Centchroman is an effective, safe, and inexpensive treatment for mastalgia and fibroadenoma, with minimal side effects such as scanty menses or amenorrhea.

Key words: Mastalgia; Fibroadenoma; Centchroman

INTRODUCTION

Approximately 50–70% of women attending any breast clinic present with mastalgia. Breast pain among women, with or without lump is common complaint and a cause of significant anxiety and fear of breast cancer.¹ Annually 200,000 breast disorders are identified² and it is noted that most of the palpable lesions are benign.³ About 50% of women in the reproductive age group experience benign breast diseases (BBD).⁴⁻¹¹ Among the BBD, mastalgia, fibrocystic disease, and fibroadenoma are the most

common. Mastalgia can be classified into two types: (1) Cyclic mastalgia: Characterized by more pain during the menstrual cycle and it is frequently related with fibrocystic breast changes or duct ectasia. Minimal tenderness during menstrual cycle is thought to be typical and is normally associated with menstrual cycle and/or premenstrual syndrome.¹²⁻¹⁴ (2) Non-cyclic mastalgia: Characterized by the pain, which is unaltered during the menstrual cycle. It has different causes and difficult to diagnose. Non-cyclical pain is not usually related with the menstrual cycle. Some level of non-cyclic breast.

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Tenderness is present because of hormonal changes in adolescence. Breastfeeding is additionally one of the reasons for non-cyclic pain. Fibrocystic breast disease is otherwise called Fibroadenosis. It is a non-carcinogenic breast condition, which presents as a diffuse lump and is connected with hormonal changes (menstrual cycle).¹²⁻¹⁶ Many women experience the ill effects of fibrocystic disease particularly in their conceptive age. Fibrocystic diseases are uncommon among menopausal women. Fibrocystic changes can happen in one or both breasts. Different pharmacological agents have been tried in the therapy of mastalgia. The drug therapy includes agents that induce hormonal manipulation such as danazol, bromocriptine, Tamoxifen, and luteinizing hormone-releasing hormone analog. Some of the effective non-hormonal agents in mastalgia are non-steroidal anti-inflammatory gels, evening primrose Vitamin E, reassurance and breast support with sports bra. There is considerable debate about drug of choice for the management of mastalgia. We present our results of antiestrogen drug “Centchroman,” It is best known as a non-hormonal, non-steroidal oral contraceptive which is taken once per week. In India, ormeloxifene has been available as birth control since the early 1990s, and it is currently marketed there under the trade name Saheli. The objective of the study was to evaluate the effectiveness of Centchroman in control of mastalgia measured by Visual Analogue Scale (VAS), and ultrasonography for breast lump.

Aims and objectives

The study aimed to assess the effect of ormeloxifene (Centchroman), a selective estrogen receptor modulator (SERM), on mastalgia and fibroadenoma.

MATERIALS AND METHODS

The study was pre-approved by the Institutional Ethical Committee before embarking in this study. This study was conducted in the Department of General Surgery of a tertiary care hospital of West Bengal for the total duration of 11 months (October 2023–September 2024) which met the inclusion and exclusion criteria after ethical committee approval. The patients were provided with a detailed printed information sheet (in Hindi or English or Bengali depending on the language understood by her) to explain about benign nature of breast pain, the currently available therapy with side effects, the potential benefits of Centchroman and its common use by Government of India as a contraceptive pill. We also informed patients about the possibility of scanty or delayed menstruation by Centchroman. Patients signed a consent form in Hindi or English or Bengali after understanding this information. The patients were

started on centchroman 30 mg on alternate days for a period of 12 weeks and were followed Sat weeks 4, 8, 12, and 24 to assess response to therapy. The results were recorded as per clinical examination, ultrasonography for breast lump size, and VAS for pain.

Inclusion criteria

Benign breast disease with a total of 104 patients up to 35 years of age. Patients with a history of breast pain. Nodularity and case of fibroadenoma with size equal to <5 cm after triple assessment.

Exclusion criteria

Patients with polycystic ovarian disease and fibroadenoma >5 cm were excluded from the study. Lactating and pregnant women. History of carcinoma breast or family history of same. Associated chest wall disorders and skin lesions along with breast disease.

RESULTS

A total of 104 patients were included in the study, 70 (67.3%) of whom had mastalgia with or without nodularity, and 34 (32.7%) had fibroadenoma. Non-cyclical pain was in 52 patients (74.28%), and cyclical pain was recorded in only 18 (25.72%) patients. A VAS score of 10 was recorded by 50 (71.43%) patients (severe pain), and the remaining 20 patients (28.57%) had VAS scores from 7 to 10 (Table 1). Fibroadenoma size ranged from 1.5 to 5 cm, single or multiple in one or both breasts. There was a good response in the mastalgia group, with a decrease in the VAS scoring from 10 to 3 in 47 (67.14%) of the patients in the 1st month. Almost all of the patients were painless at the end of 3 months, with complete disappearance of the nodularity (Figure 1). In the fibroadenoma group, there was a mixed response, with complete disappearance in 11 (32.35%), partial regression (decrease in volume of fibroadenoma) in 16 (47.05%) and no response at all in the remaining 7 (20.59%) a period of 6 months (Figure 2). There was amenorrhea or scanty menses as the only side effect.

DISCUSSION

Mastalgia can cause interference in the daily life of females, and it also raises fear and anxiety of breast carcinoma in them. In most patients with mild pain, reassurance means that the symptoms are not due to cancer is required. A Brazilian study verified a success rate of around 70.2% with reassurance in a study of 85 patients with mastalgia.⁴ The other non-medical means are dietary measures, that is, fat restriction and avoidance of methylxanthines.⁵ A randomized trial of 200 patients has revealed that the breast

Table 1: Demographic characteristics of Mastalgia and fibroadenoma

Characteristic	Numbers of patients (percentage) n=104
Age (years) Median (15–35)	
<20	20 (19.23)
21–30	65 (62.5)
31–35	29 (27.88)
Symptoms	
Mastalgia with or without nodularity	70 (67.3)
Fibroadenoma	34 (32.7)
Pain	
Unilateral	52 (74.29)
Bilateral	18 (25.71)
Cyclical	47 (66.1)
Non-cyclical	23 (32.9)

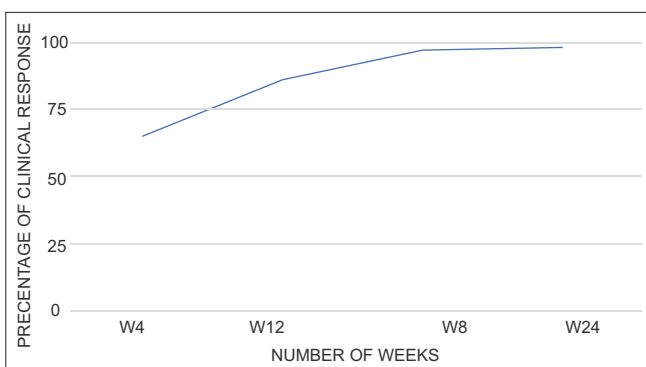


Figure 1: Clinical response (%) of mastalgia to centchroman in different weeks

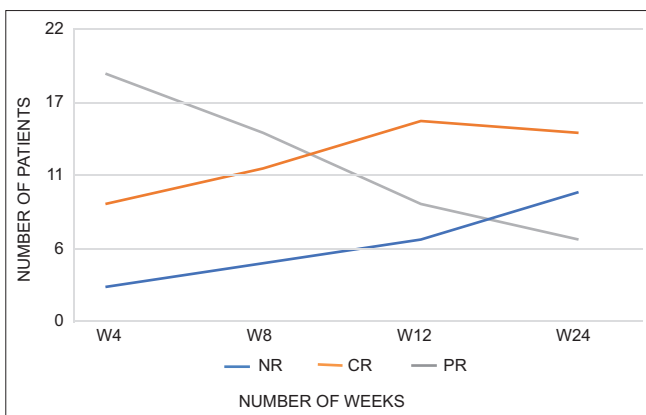


Figure 2: Response of fibroadenoma to centchroman

support with sports brassier relieved the pain in 89% of patients.⁶ The relief of pain with support garments provided by reducing the tension on overstretched Cooper’s ligament especially in women endowed with large mammary glands. There are many drugs available for the cure of mastalgia, which include bromocriptine, danazol, Tamoxifen, and topical non-steroidal anti-inflammatory drugs gels with varying side effects and efficacy.^{9,10} In a study conducted by Bhupendra Sharma, it was observed that the VAS scores in mastalgia patients were reduced to ≥ 3 .¹¹ Their results

are in unison with our study. Ormeloxifene is a novel non-steroidal, selective antiestrogen which has been used for the treatment of mastalgia and multiple small fibroadenomas. It is relatively free from adverse effects such as vomiting, nausea, dizziness, and weight gain. It does not interfere with ovulation, and hence, there is no delay in return of fertility after stopping the drug. The only adverse effect observed is delayed menses in <10% of cycles.¹² Centchroman does not have any side effects on endocrine system, liver, and lipid function, and no serious complications such as heart attack, stroke, or thrombosis are associated with it.^{10,11} Our results of ormeloxifene on multiple fibroadenoma showing complete dissolution in 32.25% partial response in 47.05% and no response in 20.59%. This is consistent with that of Dhar et al., Tejwani et al., and Gupta et al., who studied the effect of Ormeloxifene in the management of mastalgia and fibroadenoma.

Limitations of the study

Our study is a non-randomized one with a small sample size using single drug only.

CONCLUSION

Centchroman is a safe drug for the treatment of mastalgia, fibroadenosis, and fibroadenoma. It has shown good results in mastalgia and fibroadenoma, is an effective, safe, and inexpensive.

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Authors' Contributions:

SMNJ - Definition of intellectual content, prepared first draft of manuscript implementation of study protocol, data analysis, manuscript preparation and submission of article; **SJ** - Concept, design, clinical protocol, manuscript preparation, editing, and manuscript revision; **MB** - Design of study, statistical analysis, and interpretation; **IM** - literature survey, data collection.

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