



## ROLE OF ORMELOXIFENE IN NON-SURGICAL MANAGEMENT OF FIBROADENOMA

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**ABSTRACT** **BACKGROUND:** One of the most common benign tumours of the breast in the adolescent female is Fibroadenoma. Their spectrum ranges from asymptomatic masses to painful and rapidly growing tumours. The aim of the study is to evaluate the role of ormeloxifene in the conservative management of fibroadenoma. **MATERIALS AND METHODS:** The patients admitted to the Dept. Of General Surgery, MIMS, Vizianagaram with a provisional diagnosis of fibroadenoma of the breast from July 2018-June 2019, were included in the study. **RESULTS:** Total of 60 patients was evaluated, of which 40 had fibroadenoma of size more than 2 cms and 20 had fibroadenoma of size less than 2cms. Among them, around 40 (66.6%) patients had a complete response with treatment. **CONCLUSION:** Patients with fibroadenoma of size less than 2cms responded well to ormeloxifene. The response is mixed when the size is more than 2 cms. So further study has to be done to evaluate its effectiveness.

**KEYWORDS :** Benign Breast Disease, Fibroadenoma, Ormeloxifene.

### INTRODUCTION:

Fibroadenoma usually presents as a lump in the breast in young girls between ages 15 and 25 years as a discrete, firm and mobile lump.<sup>1</sup> It is considered as a component of "aberration in normal development and involution" of the breast and not a true neoplasm.<sup>2</sup>

Fibroadenoma is a condition characterised by hyperplasia of "terminal ductal lobular units". Their size can range from 1 to 3cm. Most of them remain static, but some can reach a size greater than 5 cm (giant fibroadenoma).

Multiple fibroadenomas can be seen either unilaterally or bilaterally. Nearly 10-15% of lesions regress spontaneously over a period of 6-60 months.

Simple fibroadenoma needs observation, as they are asymptomatic without any risk of further malignancy.

Complex fibroadenoma, fibroadenomas associated with atypia, symptomatic fibroadenomas (pain, discomfort, psychological reasons) needs excision

It has been described that histological sections of fibroadenoma showed the presence of estrogen receptors, and fibroadenoma is considered to arise from hyperresponsiveness of lobular tissue to oestrogen.<sup>3,4</sup> So hormonal manipulations have been attempted to suppress the growth of fibroadenoma with the antiestrogenic drug tamoxifen. Hence we use antioestrogen, ormeloxifene in order to suppress the proliferation of ductalobular tissue.

### MATERIALS AND METHODS

A total of 60 patients with a provisional diagnosis of fibroadenoma from General Surgery Outpatient Department were studied. Detailed clinical history, examination of breast and ultrasound for breast lump size. Patients are divided into two groups size <2 cms or >2 cms. Patients were started on ormeloxifene 30 mg on alternate days for 3 months and evaluated for response every month with clinical history, examination and ultrasound examination to assess any change in size and then the patient was followed for 6 months

### RESULTS

40 of 60 patients had fibroadenoma of size more than 2 cms, and 20 patients had fibroadenoma of size less than 2 cms. Among 60 patients, 40 (66.6%) had a complete response with treatment and 20 (33.3%) patients did not respond to treatment.

**Table 1 Age Distribution of Fibroadenoma Patient**

AGE	NO. OF PATIENTS	PERCENTAGE
11-15	3	5
16-20	20	33

21-25	25	42
26-30	7	12
31-35	5	8

More common in young age group between 21-25 years

**Table 2. Size Distribution of Fibroadenoma**

SIZE	NO. OF PATIENTS	PERCENTAGE
<2 CMS	20	33.3
>2 CMS-5 CMS	40	66.6

**Table 3. Response of Fibroadenoma to ormeloxifene**

WEEK	RESPONDERS	NON
4 <sup>th</sup> week	35	25
8 <sup>th</sup> week	35+10	15
12 <sup>th</sup> week	45	15
24 <sup>th</sup> week	40	15+5

- Patients who did not respond to 30 mg (alternate days) of ormeloxifene for 4 weeks, the dose was increased to 60mg on alternate days.
- Surgical excision was considered for those patients who did not respond to 12 week therapy.
- Those who responded to Ormeloxifene, the drug was stopped and followed further for 12 weeks to evaluate the response.

### DISCUSSION

Fibroadenomas can be considered as the most common benign tumours of the breast in the adolescent population. The aetiology of fibroadenoma appears to be idiopathic. However, several studies show that oestrogen influences the development of fibroadenomas.

Ormeloxifene belongs to a group of drugs known as the selective oestrogen receptor modulators which act on the oestrogen receptor.<sup>5</sup> They act as Oestrogen receptor agonist at bone and antagonist at uterus and breast.

Ormeloxifene has a long-lasting and strong antagonistic activity and weak agonist activity<sup>6</sup>. It is currently used as an oral contraceptive, which is taken once per week.

### CONCLUSION

Fibroadenomas size less than 2 cms responded well to Ormeloxifene. When the size of fibroadenoma is more than 2 cms there is a mixed response, so large scale study has to be done to evaluate its effectiveness.

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