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Corresponding Author

Apurva G. Shah,
Department of General Surgery,
BJ Medical College, Ahmedabad,
Gujrat, India

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Study of Various Drugs in Aberration of Normal Development and Involution of Breast and Fibroadenosis

¹Apurva G. Shah, ¹Florina Malek and ²Nirmala Ganapathy

¹Department of General Surgery, BJ Medical College, Ahmedabad, Gujrat, India

²Department of Plastic Surgery, BJ Medical College, Ahmedabad, Gujrat, India

ABSTRACT

Mastalgia in woman is a major factor in missed work days and occasionally, the inability to complete daily tasks. A majority of these patients have disorders of normal development and involution (ANDI), more especially fibrocystic disease. Nearly 10-15% of lesions regress spontaneously over period of 6-60 months. Up until this point, only tamoxifen has been used. If efficacy is well established, Tablet Saheli (ormeloxifene), which is less expensive, readily available and has few adverse effects, will likely become the medication of choice for these individuals. Aim of the study was to investigate the role of Centchroman in regression of fibroadenosis in comparison to natural observation and study the association of hormonal receptors with degree of regression. At the Civil Hospital in Ahmedabad, a prospective study involving 60 patients with fibrocystic breast disease and mastalgia was conducted from July 2020 to June 2023. Patient with congenital abnormalities, infectious diseases and benign breast disorders like fibroadenoma were excluded. Our research's objective was to examine the efficacy of several medications frequently prescribed for fibroadenosis and mastalgia. About 60 individuals were taken in study, 30 received Tab. Saheli (ormeloxifene), 26 received evening primrose oil and 4 received danazol. About 18 patients out of 30 got a full response to Tab Saheli (ormeloxifene), or 60% of the patients. About 50% (13 patients) of the 26 patients who started taking evening primrose oil and 50% (2 patient) of the 4 patients who started taking danazol had a full recovery. Even six months later, the remaining 27 (35%) patients' problems remained unrelieved.

INTRODUCTION

Periodic mastalgia in female patients is a significant factor in missed work days and occasionally, the inability to complete daily tasks^[1,2]. Every year, 2,000 breast disorders are discovered and the majority of palpable lesions are benign. The majority of women in the reproductive age range have benign breast disease. The most prevalent are mastalgia, fibrocystic disease and fibroadenoma. Breast pain is indicated by mastalgia. It is divided into two categories:

- **Cyclic mastalgia:** This condition is characterized by increased pain throughout the menstrual cycle and is commonly associated with duct ectasia or fibrocystic breast abnormalities. The menstrual cycle and/or premenstrual syndrome are typically linked to minimal discomfort during the menstrual cycle, which is considered to be typical
- **Non-cyclic mastalgia:** This condition is characterized by pain that is constant throughout the menstrual cycle. This kind is not typical. It has a variety of origins and is challenging to diagnose certain non-cyclic breast cancer

Teenage years, pregnancy and menopause all involve hormonal changes that produce pain. Breast feeding is additionally one of the reasons for non-cyclic pain. Fibrocystic breast disease is otherwise called Fibroadenosis^[3]. It is non carcinogenic breast condition, which presents as a diffuse lump and is connected with hormonal changes (menstrual cycle)^[4]. Many women experience the ill effect of fibrocystic disease particularly in their conceptive age. Fibrocystic disease are uncommon among menopausal women. Fibrocystic changes can happen in one or both breast.

Centchroman (ormeloxifene) is a nonsteroidal antiestrogen drug developed by the Central Drug Research Institute, Lucknow, India. It is selective estrogen reseptor modulator with weak agonist (on endometrium) and strong antagonist (on breast ductolobular epithelium) action^[5]. Till date except for tamoxifen no specific drugs were used. As compared to those drugs, ormeloxifene is cheap, easily available with minimum side effects and convenient dosage of twice a week makes in the drug of choice of such patients, if efficacy is well proved. If its efficacy is well established, ormeloxifene will likely be the medication of choice for these individuals because it is less expensive, simpler to obtain, has less side effects and only needs to be taken twice weekly^[6].

Objectives: The purpose of this research is to examine how different medications are used, with a focus on Tab. Saheli's (Ormeloxifene) function in the treatment of ANDI and breast fibroadenosis, with follow-ups at 0-, 1- and 6-month intervals.

MATERIALS AND METHODS

A prospective study of 60 patients with fibrocystic illness was conducted at Civil Hospital between July 2020 and June 2023, including female patients between the ages of 16 and 50. The study hasn't covered any specific years as of yet, with the exception of tamoxifen. The use of clinical medications was also discussed. If there was a diagnostic conundrum, it was convenient to perform a breast ultrasound in women aged less than 35 year and mammography in women aged more than 35 year along with a clinical examination.

Exclusion criteria: Patients who underwent clinical, imaging and cytological evaluation and had a distinct lump suspected to be cancer were not included in the study. Women who were nursing, planning a pregnancy, or taking any other oral contraceptives were also not included in the study. Women with polycystic ovarian disease and other hormonal issues requiring further testing, as well as liver and kidney issues, were also disqualified from the trial.

Patients were monitored after 1 month of using Tab Saheli (Ormeloxifene) at a dose of 30 mg twice weekly. After 1 month patient symptom were assessed by decrease in pain as per Visual Analogue Scale or decrease in nodularity as per Lucknow-Cardiff breast nodularity scale. If the patient's symptoms were completely gone after a month, Tab. Saheli (ormeloxifene) was discontinued. If the patient experienced only a small amount of alleviation or none at all, the dose was increased to 60 mg twice a week and the patient was reassessed at the one-month mark. The dose was increased to 120 mg twice a week if there was still no improvement and the patient was reassessed after one month (Fig. 1).

Patients were monitored after one month of taking one gram of evening primrose oil three times per day. If the patient's symptoms were fully relieved, the dose was decreased to 1 g twice a day and the patient was reassessed after 1 month. The dose was increased to 1 g four times a day if there was still no improvement and the patient was reassessed at 1 month. Patients were monitored after one month of taking danazol at a dose of 200 mg twice daily. If the patient's symptoms were fully relieved, the dose was decreased to 100 mg twice a day and the patient was reassessed after one month (Fig. 2). The dose was increased to 300 mg twice a day if there was still no improvement and the patient was reassessed after one month. At each subsequent appointment, the patients' symptoms of mastalgia and fibroadenosis were evaluated for improvement. A complete response was characterized as the removal of symptoms, a partial response as a partial resolution of symptoms and no reaction as neither a change in symptoms nor a worsening of symptoms.



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Fig. 2: Daily breast pain chart

About 18 out of the 30 patients who started taking Tab. Saheli (ormeloxifene) 30 mg twice a week were relieved their symptom at the end of 1 month and 10 patient were relieved their symptom after 6 month with increase dose of Saheli (Ormeloxafene). The rest 2 patient was not relieved their symptom even after 6 month. 13 patients, or 50%, of the 26 patients who began using evening primrose oil saw a full recovery were 11 patient developed partial response and 2 patient do not responded. About 50% (2 patients) of the 4 patients who were started on danazol experienced a full recovery and 1 have partial response were 1 do not respond to Tab Danazol^[7]. Even after receiving treatment for six months, 27 of the remaining patients (35%) did not obtain symptom improvement (Table 1).

10-20 years and 21-30 years the patient presented chiefly with the complaint of mastalgia (10 and 12%, respectively). Out of 60 patients with ANDI and fibroadenosis includes in the study, 30 patient were given tab Saheli (Ormiloxafene) and 18 patient benefitted from it. There was improvement in both the nodularity and mastalgia.

Gupta^[9] Prospective study the efficacy and side effect of orniloxafene in regression of mastalgia and fibroadenoma. In this study 97.6 to 100% of women in mastalgia group are reported complete relief at 12 week of therapy, during follow up after the end of study period 3% patient returned with the complaint of pain with a VAS scoring of 2-5 (mild pain). These were again put on drug therapy at decreased frequency of drug administration (once a week for 3 month) with a good response.

About 81 patient with mastalgia were studied. About 39 were randomized to Danazol and 42 in centchroman (ormiloxafene) treatment given for 12 week followed by observation for 12 week. At 12 weeks 89.7% women achived pain reduction on centchroman (ormiloxafene) and 69.44% women

Table 1: Management of mastalgia and types of response (Total = 60)

Variables	Complete response	Partial response	No response	Total
Evening primrose oil	13	11	2	26
Saheli (ormeloxifene)	18	10	2	30
Danazol	2	1	1	4
Total (%)	33 (55%)	22 (36.6%)	4 (6.67%)	60 (100%)

achieved reduction in pain on danazol. Three months after stopping therapy, Centchroman was more effective in pain score reduction at 24 week as compared to Danazol.

CONCLUSION

The outcomes of this prospective trial indicate that Tab. Saheli (ormeloxifene) is an efficient mastalgia and fibroadenosis therapy choice. In contrast to danazol (50%) and evening primrose oil (50%), it showed a higher complete response rate (60%). Patients prefer Tab. Saheli because of the practical twice-weekly dosage and the few adverse effects. Female patients who used Tab. Saheli (ormeloxifene) reported that it was highly effective at reducing their symptoms of mastalgia and fibroadenosis. Compared to the other medications examined, it showed a higher rate of full responses. It is a viable alternative for the management of these conditions due to the ease of its dose schedule and its few side effects. These results need to be confirmed and larger trials are required to determine the long-term safety and effectiveness of Tab. Saheli in the treatment of mastalgia and fibroadenosis.

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