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A Comparative Study in the Efficacy of Tamoxifen Vs Efficacy of Ormeloxifen In Benign Proliferative Breast Diseases

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Abstract:
OBJECTIVES:
Centchroman (Ormeloxifene) is a novel non-steroidal, selective antiestrogen. Because of its selective antiestrogen action, centchroman has been used for treatment of mastalgia and fibroadenoma. Tamoxifen is an older congener of the same which is used widespread for the benign breast diseases. Our aim is to compare the efficacy of both drugs in similar selected group of patients.
MATERIALS AND METHODS:
100 Benign breast disease patients up to 35 years of age attending our surgery outpatient department from 2017 to 2018 and fulfilling the inclusion criterion were included in this study. Group A -50 were started on centchroman 30 mg on alternate days for a period of 3 months and were followed up for 6 months. Remaining (Group B) 50 were started on Tamoxifen 20 mg for 3 menstrual cycles Results were recorded as per clinical examination and ultrasonography for breast lump size VAS scale for pain.
RESULTS:
A total of 100 patients were included in this pilot study, (70%) of whom had mastalgia with or without nodularity, and (30%) had fibroadenoma. Noncyclical pain was recorded in (90%), and cyclical pain was recorded in only (10%) patients. Fibroadenoma size ranged from 1.5 to 5 cm., single or multiple in one or both breasts. In Group A there was a good response in the mastalgia group, with. Almost all of the patients were painless at the end of one month, with complete disappearance of the nodularity. In the fibroadenoma group there was a mixed response, with complete disappearance in 60%, partial regression in 20%, and no response at all in the remaining 20%. In Goup B 60% showed improvement with regard to painful symptoms,60% showed partial disappearance of lump 6.6% complete regression and 33.3% no response at all.
CONCLUSIONS:
Centchroman is a safe nonsteroidal drug for the treatment of mastalgia and fibroadenoma. It has shown good results in mastalgia and is a safe drug as compared to tamoxifen. Further randomized studies are in progress and are needed to determine its definitive role in this patient group.
Keywords: *Benign breast diseases,fibroadenoma,mastalgia,ormeloxifen,tamoxifen.*

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I. Introduction

Ormeloxifene, also known as **centchroman**, is one of the selective estrogen receptor modulators. or SERMs, a class of medication which acts on the estrogen receptor.Ormeloxifene is a selective estrogen receptor modulator (SERM). In some parts of the body, its action is estrogenic (e.g., bones), in other parts of the body, its action is antiestrogenic (e.g., uterus, breasts).[11][12] It causes an asynchrony in the menstrual cycle between ovulation and the development of the uterine lining, although its exact mode of action is not well defined. In clinical trials, it caused ovulation to occur later than it normally would in some women,[7] but did not affect ovulation in the majority of women, while causing the lining of the uterus to build more slowly. It speeds the transport of any fertilized egg through the fallopian tubes more quickly than is normal.[7] Presumably, this combination of effects creates an environment such that if fertilization occurs, implantation will not be possible.[7]

Tamoxifen (**TMX**), , is a medication that is used to prevent breast cancer in women and treat breast cancer in women and men.[3] It is also being studied for other types of cancer.[3] It has been used for Albright syndrome.[4] Tamoxifen is typically taken daily by mouth for five years for breast cancer.[4]

Serious side effects include a small increased risk of uterine cancer, stroke, vision problems, and pulmonary embolism.[4] Common side effects include irregular periods, weight loss, and hot flashes.[4] It

may cause harm to the baby if taken during pregnancy or breastfeeding.[4] It is a selective estrogen-receptor modulator (SERM) that works both by decreasing factors that increase the growth of breast cells and increasing factors that decrease the growth of breast cells.[4][5] It is of the triphenylethylene group

II. Aims And Objectives

Our aim is to study the efficacy of both the drugs in treating benign breast diseases.Also to study the risk benefit ratio in using these drugs.the effects are similar but the efficacy could be different and adverse reactions could be different in two drugs belonging to the same group.

III. Materials And Methods

100 Benign breast disease patients up to 35 years of age attending our surgery outpatient department from 2017 to 2018 and fulfilling the inclusion criterion were included in this study. Group A -50 were started on centchroman 30 mg on alternate days for a period of 3 months and were followed up for 6 months. Remaining (Group B) 50 were started on Tamoxifen 20 mg for 3 menstrual cycles Results were recorded as per clinical examination and ultrasonography for breast lump size VAS scale for pain.

Patients were classified in to 2 groups randomly and were blinded on the drug whic they were prescribed. A proper consent was obtained from the patients and an ethical approval was obtained prior to the commencement of the study.

INCLUSION CRITERIA.

Benign breast diseases like fibroadenoma,fibroadenosis,cyclical mastalgia,non-cyclical mastalgia.

Patients were categorised based on clinical,sonographic,FNA evaluation.

EXCLUSION CRITERIA

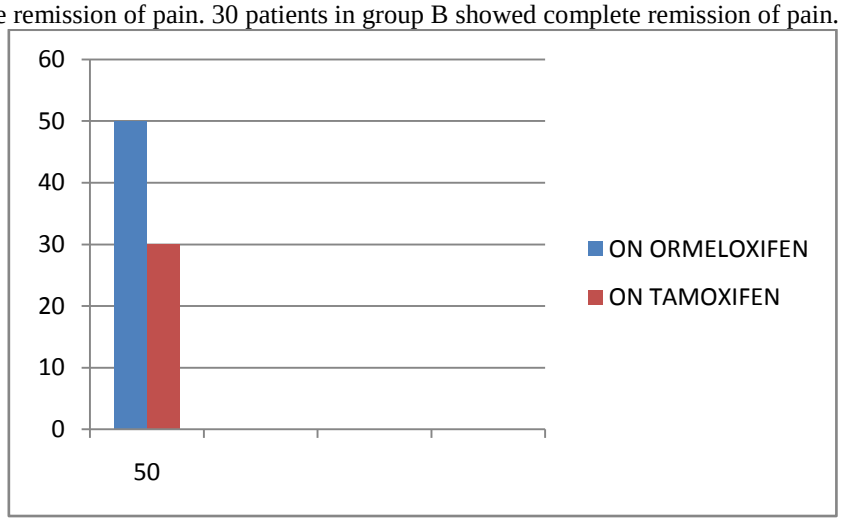
Patients on steroids,on HRT,on OCP,on chemotherapy .

IV. Results

Results were analysed and statistically tabulated.

TABLE 1: RESPONSE TO PAIN

All 100 patients had pain before treatment.after the course of their respective treatments 50 patients in group A showed complete remission of pain. 30 patients in group B showed complete remission of pain.

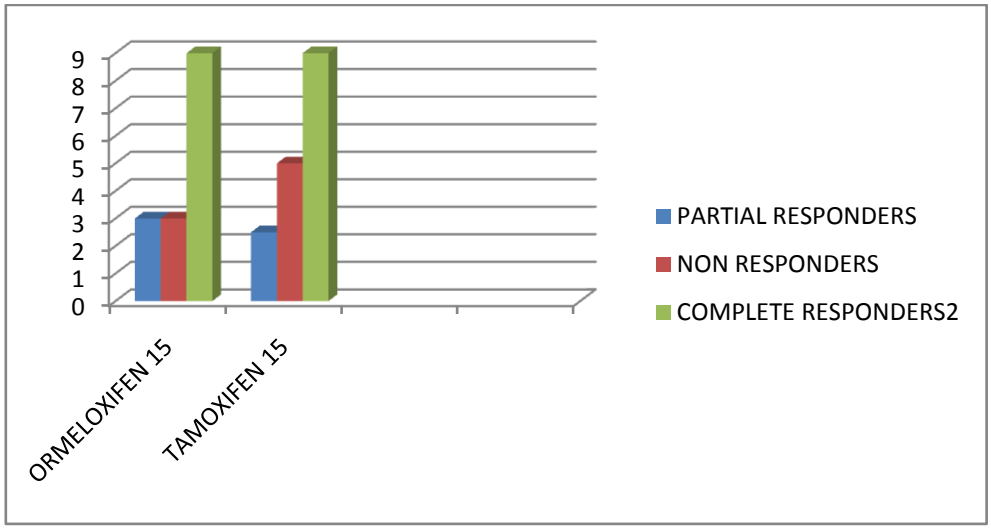


Breast lump was a specific complaint in 30 patients of the total 100. Those 30 patients were divided randomly into 2 groups of 15 patients in each and were subjected to the drug therapy.

In Group A 9 patients showed complete regression of the lump,3 patients showed partial regression and 3 patients did not show any response at all.

In Group B also 9 patients showed complete regression of the lump, but only1 patient showed partial regression and remaining 5 patients did not show any response at all.

TABLE 2: REGRESSION OF FIBROADENOMA



V. Discussion

The vast majority of the lesions that occur in the breast are benign. Much concern is given to malignant lesions of the breast because breast cancer is the most common malignancy in women in Western countries; however, benign lesions of the breast are far more frequent than malignant ones [1–9]. With the use of mammography, ultrasound, and magnetic resonance imaging of the breast and the extensive use of needle biopsies, the diagnosis of a benign breast disease can be accomplished without surgery in the majority of patients. Because the majority of benign lesions are not associated with an increased risk for subsequent breast cancer, unnecessary surgical procedures should be avoided. It is important for pathologists, radiologists, and oncologists to recognize benign lesions, both to distinguish them from in situ and invasive breast cancer and to assess a patient's risk of developing breast cancer, so that the most appropriate treatment modality for each case can be established.

The term "benign breast diseases" encompasses a heterogeneous group of lesions that may present a wide range of symptoms or may be detected as incidental microscopic findings. The incidence of benign breast lesions begins to rise during the second decade of life and peaks in the fourth and fifth decades, as opposed to malignant diseases, for which the incidence continues to increase after menopause, although at a less rapid pace [2–14].

Acute Mastitis,granulomatous mastitis,sub areolar abscess,mammary suct ectasia,intraductal pappilloma,fat necrosis,breast cyst,adenosis,metaplasia,diabetic fibrous mastopathy,cyclical or non cyclical mastalgis,pseudoangiomatous stromal hyperplasia of breast,lipoma,adenoma,hamartoma are some of the entities that come under benign breast diseases.Most common of all is the mastalgia of unknown reasons and fibrodenosis or adenoma of breast.

Many drugs have been tried in the treatment of these conditions.Selective Estrogen Receptor Modulators have been used for ages since their invention. Of those tamoxifen and ormeloxifen have been used commonly.

Tamoxifen is currently used for the treatment of both early and advanced estrogen receptor-positive (ER-positive or ER+) breast cancer in pre- and post-menopausal women.[10] Additionally, it is the most common hormone treatment for male breast cancer.[11] It is also approved by the FDA for the prevention of breast cancer in women at high risk of developing the disease.[12] It has been further approved for the reduction of contralateral (in the opposite breast) cancer. The use of tamoxifen is recommended for 10 years

Endometrial cancer

Tamoxifen is a SERM. Even though it is an antagonist in breast tissue it acts as partial agonist on the endometrium and has been linked to endometrial cancer in some women. Therefore, endometrial changes, including cancer, are among tamoxifen's side effects. With time, risk of endometrial cancer may be doubled to quadrupled, which is a reason tamoxifen is typically only used for 5 years.

The American Cancer Society lists tamoxifen as a known carcinogen, stating that it increases the risk of some types of uterine cancer while lowering the risk of breast cancer recurrence The ACS states that its use should not be avoided in cases where the risk of breast cancer recurrence without the drug is higher than the risk of developing uterine cancer with the drug.

Cardiovascular and metabolic

Tamoxifen treatment of postmenopausal women is associated with beneficial effects on serum lipid profiles. However, long-term data from clinical trials have failed to demonstrate a cardioprotective effect. For some women, tamoxifen can cause a rapid increase in triglyceride concentration in the blood. In addition there is an increased risk of thromboembolism especially during and immediately after major surgery or periods of immobility. Tamoxifen is also a cause of fatty liver, otherwise known as steatorrhoeic hepatosis or steatosis hepatis.

Central nervous system

Tamoxifen-treated breast cancer patients show evidence of reduced cognition, a major side effect of tamoxifen, and semantic memory scores. However memory impairment in patients treated with tamoxifen was less severe compared with those treated with anastrozole (an aromatase inhibitor).

A significant number of tamoxifen-treated breast cancer patients experience a reduction of libido.

Premature growth plate fusion

While tamoxifen has been shown to antagonize the actions of estrogen in tissues such as the breast, its effects in other tissues such as bones has not been documented fully.

VI. Conclusion

Benign breast diseases of breast covers a wide spectrum of disorders under its belt. In our set up the commonest presenting complaints of patients with regard to breast are mastalgia and adenoma. Ormeloxifen used in its management has more response and less adverse affects compared to tamoxifen which belongs to to the same group.

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