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A Prospective Study to Review the Outcome of Ormeloxifene in Fibrocystic Diseases to Reduce Mastalgia and Nodularity

Dr. Neha Ranjan[1], Dr. Tejaswini Jain[2], Dr Pankaj Kumar[3]

[1]Senior Resident, Surgery Department, JLNMCH Bhagalpur

[2]Junior Resident, Surgery Department, JLNMCH Bhagalpur

[3]Associate Professor, Surgery Department, JLNMCH Bhagalpur

Abstract: ***Aim: A prospective study to review the outcome of ormeloxifene in fibrocystic diseases to reduce mastalgia and nodularity. Objectives: 1) To describe fibrocystic diseases of breast.2) To describe the management options available.3) To describe how ormeloxifene is better in medical management. Methods: Patients complaining about breast pain with fibrocystic changes, are treated on an outpatient basis by prescribing ormeloxifene 30 mg twice a week for 3 - 6 months. Inclusion criteria: Female Patients of age group 2nd - 3rd decade, having complaints of cyclic or non cyclic mastalgia with FNAC proven fibrocystic changes. Exclusion Criteria: Female patients age group of more than 40yr.1) Patients having giant fibroadenoma FNAC proven).2) Patients having breast lump with lymphadenopathy.3) Patients not giving consent for ormeloxifene.4) Women who were planning pregnancy in the near future and pregnant women.5) Women with abnormal and undiagnosed uterine bleeding. Results: Total 60 cases were studied. Mastalgia has been improved by 90% in 54 patients within one month of starting ormeloxifene. There is 30% decrease in nodularity after taking drug continuously for 3 months. Conclusion: Ormeloxifene is non steroidal and non hormonal drug having both estrogen agonist and antagonist properties, and approx 47% antineoplastic property. Ormeloxifene has more positive results in reducing mastalgia and nodularity and lesser side effects than other modalities (danzole tamoxifen).***

Keywords: fibrocystic diseases, mastalgia Treatments, ormeloxifene, breast nodule, non hormonal management

1. Introduction

Benign breast diseases (BBD's) are commonly seen among the younger age group with incidence peaking in second and third decades. Most of the women experience a lump with or without pain which inflicts fear of malignancy and gets the patient to the breast clinic, out of which 2/3rd are benign. Yearly 200, 000 patients visit a surgeon with palpable breast lump of which most of the palpable lesions are benign. Most benign disorders are derived from minor aberrations of the normal process of development, cyclical hormone - related change and involution. To address this confusion, the concept of Aberrations of Normal Development and Involution (ANDI), developed. It helps in better understanding and treatment of benign breast disease.50% women throughout their reproductive life will suffer from BBD's at some point of time. The most common complaint in patients with BBD is breast lump or breast nodularity (42%) and breast pain (66%). Fibrocystic breast disease otherwise termed as fibro adenosis which comes under non - carcinogenic breast condition. exhibits as diffuse lump with or without pain. which is highly associated with hormonal changes at the time of menstrual cycle. Women faces fibroadenosis particularly in their conceptive age which affects one or both breasts. Hence, a new agent named ormeloxifene taken into account. Ormeloxifene is a selective estrogen receptor modulator and a class of medication which otherwise known as centchroman in India. It was introduced by central drug research institutes as an oral contraceptive in the National Family Welfare Program India, in 1995. Ormeloxifene had an advantage over the other steroidal oral contraceptives in not having side effects like nausea, vomiting, weight gain and dizziness. During the study, it showed 90% improvement at a dose of 30 mg taken on twice weekly. In this study, we observed the outcome to which ormeloxifene diminish the pain, reduces the size of the lump and decreases nodularity in patients suffering from three most common etiological benign breast diseases, fibroadenoma, fibroadenosis and mastalgia.

2. Material and Methods

The study on benign breast diseases conducted in the General surgery department of Jawaharlal Nehru Medical College and Hospital, Bhagalpur from 2023 to 2024 after getting prior approval from the ethical committee. A prospective clinical study was conducted for 24 weeks considering the total number of patients to be 70 in which 60 were taken into account. The study had patients who came with complaints of a Breast lump or pain who were below the age group of 30 years. Patients were then segregated into three arms fibroadenoma, fibroadenosis and mastalgia based on triple assessment. All women before inclusion in the study were subjected to imaging studies either ultrasound examination or mammography as indicated. FNAC of any lumps detected and cytological studies of the breast secretions if present were also carried out to rule out malignancy. we used was score for mastalgia, Lucknow - Cardiff scale (LCS) to know the grade of nodularity in a non - discrete lumpy breast.

3. Observation

In course of follow up, we used Lucknow - Cardiff scale (LCS) to know the grade of nodularity in a non - discrete lumpy breast, VAS score for mastalgia. Each time the increment, decrement and disappearance in lump, nodularity and pain in documented and the percentage recorded. The outcomes assessed based on patients condition symptomatically and the side effect.

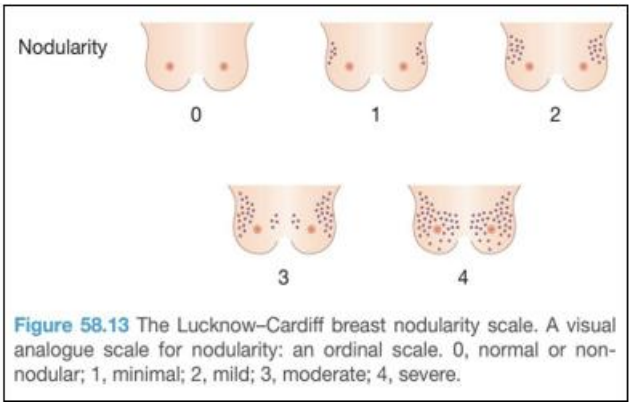
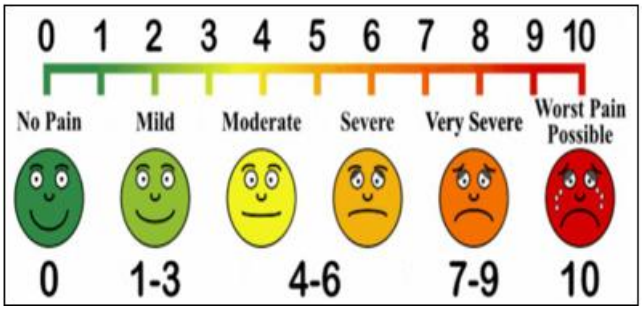
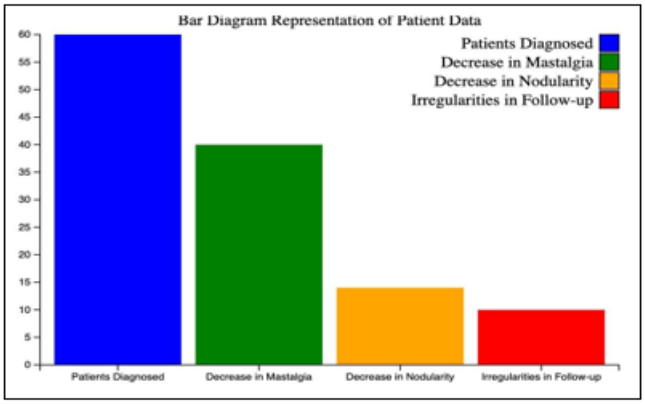


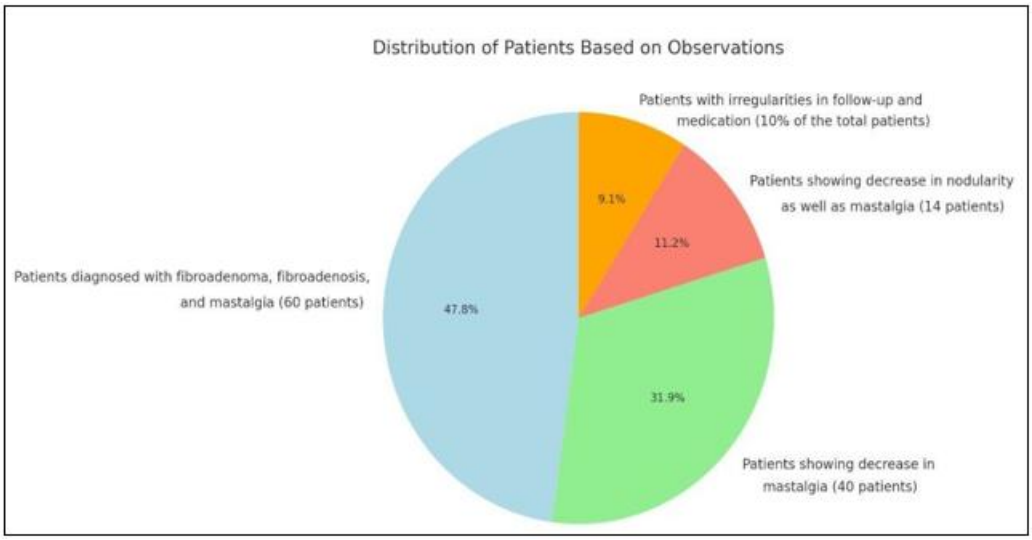
Figure 58.13 The Lucknow–Cardiff breast nodularity scale. A visual analogue scale for nodularity: an ordinal scale. 0, normal or non-nodular; 1, minimal; 2, mild; 3, moderate; 4, severe.



4. Results

We included 70 patients in this study in which 10 patients show lack of participation and hence these patients were excluded from study and study were performed with 60 patients. These 60 patients were diagnosed with fibroadenoma fibroadenosis and mastalgia. In which 40 patient show decrease in mastalgia, vas score was decreased up to 1 and 0.14 patients show decrease in nodularity as well as mastalgia.10% patients failed to follow up clinic visit and irregularities in taking medication, these having less or minimal effect on their symptoms.





5. Discussion

In India, benign breast diseases started its journey in the 2nd decades and got its accelerated state at 4th or 5th decades. The most common benign breast lump was a fibroadenoma. The second most crucial lesion is fibrocystic diseases which otherwise termed as fibroadenosis that accounting for 21.12% with age limit of above 26 years of age. It seen among young women especially under the age of 30.32 Godwins et al stated in their study that the highest number of cases registered at the age of above 30 years Amr et al exhibited that maximum age limit for incurring fibroadenosis between the age of 31 - 35 years. The third most crucial lesion is mastalgia which prevails among many young women. Generally, mastalgia experienced by women under the age category of 55 years. Hence the present study considers a very meagre amount of respondents who affected with mastalgia. However, respondents for our research is under the age category of below 30 years. Mastalgia has been broadly classified into

cyclical, non - cyclical and extramammary. In cyclical mastalgia discomfort most commonly occurs around the menstrual cycle or ovulation. It is usually seen 2 to 3 days premenstrual. This is typically characterised by fine nodularity of breast prior to menstruation which subsides post menstrually. When the pain or discomfort lasts for more than a week per cycle and restricts her activities it is considered significant. The three hormonal theories were regarded as the aetiology of mastalgia and nodularity. Increased oestrogen secretion from the ovary, deficient progesterone production (relative hyperestrogenism) and hyperprolactinemia were put forward. True non - cyclical mastalgia occurs in both premenopausal and postmenopausal women. This pain is well localised to the breast especially in the sub - areolar and upper outer quadrants of the breast. Normally the intensity and nodularity is less pronounced than in the cyclical mastalgia. Non Cyclical mastalgia in fact responds better to hormonal therapy Than musculoskeletal pain.

Management of mastalgia: Treatment begins with assessment, including breast examination and imaging. If normal, reassurance that the symptoms are not due to cancer helps the majority of women. The type of pain, cyclical or non - cyclical, should be identified by recording a pain chart for 1 month. Psychological assessment and support forms an integral part of the management of mastalgia owing to these stress levels.

Ormeloxifene: Ormeloxifene (Centchroman - C30 H35 NO3) is a non - steroidal, third generation selective oestrogen receptor modulator (SERM) that antagonises the effect of oestrogen on uterine and breast tissue and agonises its effects on vagina, bones, CVS and CNS. Ormeloxifene binds competitively to the oestrogen receptors and antagonises oestrogen induced gene expression. It elicits weak oestrogen agonistic and potent antagonistic activities but is devoid of progestational, androgenic, and antiandrogenic activities. There is an early return of fertility after stopping this drug; therefore it is safe in the treatment of unmarried women and those who wish to conceive after treatment. No teratogenic effect has been observed yet. Women who conceived while on treatment gave birth to healthy children in the phase III multicenteric contraceptive trials during research. In our study we tried to figure out the efficacy of Ormeloxifene in relieving mastalgia and nodularity. We have restricted the study to benign breast pain which is an ordeal in a women's day to day life socially and sexually. It was a prospective cohort and all the eligible patients participated in the study. In our study Ormeloxifene was found to be very useful in relieving mastalgia as well nodularity effectively irrespective of the etiology.

TABLE 58.2 Treatment of breast pain.

Exclude cancer	
Reassure	Use a VAS breast pain chart to record severity
Adequate support	Tight sports brassiere during the day
Consider medication	
Flax seed 30 g daily or oil of evening primrose	Rich sources of omega 3 fatty acids and γ-linolenic acid, respectively
Topical non-steroidal anti-inflammatory cream (diclofenac or piroxicam) four times a day	Useful in mild to moderate mastalgia
Consider systemic medication if pain score >3 on a VAS of 0-10	
Tamoxifen 10 mg daily	For 3–6 months
Danazol 50–300 mg daily	For 3–6 months
Ormeloxifene 30 mg twice a week	For 3–6 months used in both cyclical and non-cyclical mastalgia and for treating nodularity
LHRH agonist alone or with antioestrogen: tamoxifen or ormeloxifene	Short duration: use for 3 months for recalcitrant pain not relieved by the above medications

6. Conclusion

Ormeloxifene is non steroidal and non hormonal drug having both estrogen agonist and antagonist properties, and approx 47% antineoplastic property. Ormeloxifene has more positive results in reducing mastalgia and nodularity and lesser side effects than other modalities (danzole tamoxifen). Ormeloxifene had an advantage over the other steroidal oral contraceptives in not having side effects like nausea, vomiting, weight gain and dizziness. The other added benefit was its less frequent administration of twice weekly regimen. Return of fertility was not delayed. Owing to its low dosage and less frequent administration, any effect over the hypothalamic - pituitary axis is minimal; hence normal ovulatory cycles are resumed after withdrawal of the drug.

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