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# MANAGEMENT OF MASTALGIA : A CLINICAL CHALLENGE

KEYWORDS

Mastalgia, Centchroman, Danazole, Tamoxifen, Clinical Challenge

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**ABSTRACT**

***INTRODUCTION:*** *Breast pain or mastalgia is one of the most common benign condition of the breast coming to surgical OPD. Patients come to clinician either to rule out breast cancer or for the treatment of depression & anxiety associated with mastalgia and hence all patients with mastalgia must be thoroughly examined, investigated and adequately managed.*

***METHODS:*** *220 patients, who had mastalgia for more than 3 months, were treated with Centchroman 30 mg daily ,Danazol 100 mg daily and Tamoxifen 10 mg daily. Treatment was continued for 2 months with all these medicines. Some of the patients who did not respond well either with Danazol or Tamoxifen or Centchroman were further treated with Centchroman for 2 more months.*

***RESULTS:*** *220 Patients of mastalgia were taken into consideration in this study. Out of these 143 were having Cyclical mastalgia and 77 were having non-cyclical. Cyclical mastalgia was commoner in younger age group than non-cyclical. Treatment was started in both the groups with either Centchroman or Danazol or Tamoxifen.The patients were followed up for 2 months.Those patients not showing good response with Tamoxifen or Danazol or Centchroman were further treated with Centchroman for 2 more months. Satisfactory results were noted with Centchroman.*

***CONCLUSION:*** *This study has demonstrated that Centchroman therapy is found safe and cost effective . It helps in improving the quality of life by its high cure rate in comparison with Danazol and Tamoxifen.*

## INTRODUCTION

Breast pain or mastalgia is the most common complain in female patients attending surgical OPD or breast clinic [1]. It is also the most common benign condition of the breast and often poorly understood. Approximately 60 to 70 % of women experiences some degree of breast pain at some stages of their lives, and in 10 to 20 % of cases , it is severe [2,3]. The two most common concerns of patients seeking advice are : the fear of breast cancer and the presence of severe pain affecting their day-today life. Majority of the patients with mastalgia can be managed with reassurance and simple analgesics. Mastalgia is often associated with breast nodularity that may be tender or without a discrete lump. Some amount of breast nodularity and mastalgia are found in normal population [3].

Mastalgia may be cyclical or non-cyclical, intermittent or constant, localized or diffuse. Non-cyclic mastalgia can be either arising from breast tissue or it can arise from chest wall e.g. Tietze's syndrome [4]. Non-cyclical mastalgia is defined as intermittent or continuous breast pain without premenstrual exacerbation.

Cyclical mastalgia is defined as breast pain with either only premenstrual exacerbation or pain throughout the month with premenstrual exacerbation [5]. In most of the cases , no physical cause is determined and very little response is obtained from the given medical treatments.

In spite of all radiological and medical developments, the etiology of mastalgia is not fully enlightened. There is a relationship determined between mastalgia with depression, anxiety and psychological symptoms. Mastalgia has also been found to be related to high stress level [4,6,7].

So aim of this study is to relieve depression, anxiety, psychological symptoms and heavy stress in women suffering from mastalgia by providing reassurance, breast support brassiere and effective medicines to improve quality of life.

### Materials and Methods

The study was carried out in 220 cases of mastalgia coming to the Surgery OPD of MGM Medical College & Hospital, Jamshedpur between May,2014 and April,2016. The age of the patient selected for this study were between 17 to 60 years. Eligible patients, who had mastalgia for more than 3 months were selected for the study. Assessment of the patient begins with clinical examination, mammography and fine needle aspiration cytology where indicated. If these investigations exclude overt pathology the condition is explained to affect the quality of life, the patient is asked to complete a breast pain chart for a period of at least two menstruation cycles. This provides a baseline measurement of the pain's severity and allows classification into cyclical and non-cyclical mastalgia [4].

This division is important as the chances of obtaining a useful response to drug treatment are different for the two conditions, non-cyclical mastalgia tending to be more resistant to treatment than cyclical. Musculo-skeletal pain in the form of Tietze's syndrome and chest wall pain , may also present as breast pain. Careful examination is important to differentiate the musculo-skeletal pain from breast pain as musculo-skeletal pain does not respond to hormonal therapy but may be improved by local injection of steroid and local anaesthetic [8].

If the pain continues the patient is started on either Centchroman 30mg daily, Danazol 100mg daily or Tamoxifen 10mg daily . The choice of the most appropriate treatment is made with the patient, taking account of the chances of improvement with each drug and the potential side effects. The treatment is continued as long as there are no significant side effects and each patient is reviewed after 2 months. The treatment is given for 4 months and then stopped.

## RESULTS

220 cases of mastalgia were included in this study. 143 (65%) of patients had cyclical mastalgia and 77 (35%) had non-cyclical mastalgia. The patients with costocondral pain, breast lump, nipple discharge, pregnancy, lactation & breast carcinoma were excluded from the study group.

**Table No. 1 : Showing Frequency of Mastalgia**

| Diagnosis | No. of Patients | Percentage (%) |
|---|---|---|
| Cyclical Mastalgia | 143 | 65% |
| Non-Cyclical Mastalgia | 77 | 35% |

The range of age of the patients with cyclical mastalgia was 17 to 40 years (median age 31years). The range of non-cyclical mastalgia was 23 to 60 years(median age 36 years).Thus patients with cyclical mastalgia were younger than those with

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non-cyclical mastalgia ( Table-2).

**Table 2 : Age range of the patients**

| Age Range | Cyclical Mastalgia Frequency | Non-cyclical Mastalgia Frequency |
|---|---|---|
| < 20 years | 08 | 00 |
| 21-30 years | 41 | 20 |
| 31-40 years | 94 | 47 |
| 40 to 50 years | 00 | 08 |
| 50 to 60 years | 00 | 02 |
| Total | 143 | 77 |

Cyclical Mastalgia :
One hundred and forty three patients received drug treatment for cyclical mastalgia. Initial treatment was with Danazol in 62 patients, Centchroman in 51 cases and Tamoxifen in 30 patients. A clinically useful response was obtained in 50 (80.64%) of those treated with Danazol, 46 (91.19%) with Centchroman and 21 (70%) with Tamoxifen after initial 2 months treatment. In 26 patients , who did not show improvement after initial 2 months treatment with the above drugs, were again given only Centchroman 30mg daily for another 2 months period. After further 2 months period 25(96.15%) patients treated with Centchroman were found symptom free.

Non-cyclical mastalgia :
77 patients of non-cyclic mastalgia were given Danazol in 33 patients, Tamoxifen in 14 and Centchroman in 30 patients. A clinically useful response was obtained in 26(78.79%) patients of those treated with Danazol, 10(71.42%) with Tamoxifen and 27(90%) with Centchroman after 2 months treatment. In 14 patients , who did not show much relief after initial treatment, were given Centchroman 30mg daily only for another 2 months period. 12 (85.75%) patients were reported symptom free at the end of this period. 2 patients did not report to this study.

Adverse events :
The proportions of patients with cyclical and non-cyclical mastalgia complaining of significant adverse events on each drug was similar, and have therefore been combined. 19 out of 95 danazol treated patient were treated later on with Centchroman as 6 (31.57%) patients had adverse effects ( weight gain, acne ,depression, amenorrhea,voice change and hirsutism ) and 13 (68.42%) cases had no benefit. To start with 44 patients were treated with Tamoxifen,13 (29.54%) patients had adverse effects like hot flushes, vaginal dryness, low libido, mood swings, nausea and fluid retention and due to this they discontinued the treatment. Out of 81 patients treated with Centchroman initially 8(9.87%) patients had to continue their treatment for 2 more months to get adequate response. Except delayed menses Centchroman had no other side effect. The adverse effects complained of are described in Table 3 :

**Table 3 : Adverse Effects Complained of by the Patients**

| Danazol | Tamoxifen | Centchroman |
|---|---|---|
| Weight gain | Hot Flushes | Delayed mense |
| Acne | Vaginal dryness | |
| Depression | Low libido | |
| Amenorrhea | Mood swings | |
| Voice Change | Nausea | |
| Hirsuitism | Fluid retention | |

**DISCUSSION**
Breast pain interferes with the daily routine life of women and raises fear of breast cancer.

In mild pain, reassurance that the symptoms are not due to cancer, is all that is required. In the study by Barros AC, et al 1999 it was found that overall success rate of 70.2% with reassurance only is required in 85% patients of mastalgia. The other non medical means are dietary measures like fat restriction and avoidance of methylxanthines [10]. Breast support with sport's brassier in a randomized trial of 200 patients relieved the pain in 89% of patients in Minton JP,et al (1979) group of studies[11]. The support garments provide relief of pain by reducing the tension on overstretched Cooper's ligament especially in women endowed with large breast. Hence support garments should be advised in these patients.

Women without pathology on the physical examination and radiological examination were included in this study. Thus patients who did not have an underlying breast pathology, but mastalgia, were enrolled.

Although the disease occurs in any age group from 17 years to 60 years , in this study the most common age for both group of mastalgia was 31 to 40 years. The patients with cyclical mastalgia was found younger than those with non-cyclical mastalgia.

In this study, the patients were treated with Centchroman, Danazol and Tamoxifen to see the effects of these drugs on both groups of mastalgia. This study showed that Centchroman is the drug of choice because of better toleralibility, low price and very low side effects. Danazol and Tamoxifen are also found effective but due to their side effects and high cost, patients show reluctance to continue their treatment with these drugs for longer period.

In this study, Centchroman 30mg daily was found free from side effects like nausea, vomiting, weight gain and dizziness. Centchroman did not delay return of fertility ( after stopping) as it does not disturb ovulation. It had only one adverse effect , delayed menses in less than 10% of cases. It maintained normal ovulatory cycles. Centchroman had no apparent adverse effects on endocrine, hematological, liver and lipid function and also had not been associated with any serious complications like heart attack, stroke or thrombosis [12,13,14]. In this study, Centchroman was found to have response rate of more than 90% cases during the observation period of 4 months.

Tamoxifen 10mg daily given in this study of mastalgia in 44 cases were found effective in 70% cases in 2 months period [15]. In this study, Tamoxifen was found superior in non-cyclical mastalgia (71%) as compared with cyclical mastalgia [16]. It alleviated pain in at 2 months period but in 13 cases (29.54%) treatment was not so effective as to continue with same treatment. Side effects of Tamoxifen commonly observed in 2 months treatment with mastalgia include hot flushes , menstrual irregularity / amenorrhea, weight gain, nausea, vaginal dryness and bloating [17]. Thromboembolic events, endometrial cancer and cataracts are rare but serious side effects of Tamoxifen, their incidence in short term low dose treatment regimens for mastalgia is not known [16]. Although Tamoxifen is cheaper drug but patient compliance was less because of its side effects and the misconception of it being an anti cancer drug in 29.54% cases of this study.

The this study, Danazol 100 mg daily was given in both group of mastalgia with good response rate of 71% to 80% [18,19]. Danazol was found more effective in cyclical mastalgia (80.64%) cases than non-cyclical mastalgia (78.79%) [20]. The side effects observed in this study were weight gain, acne ,depression, amenorrhea, voice change and hirsutism [18]. Use of Danazol in the luteal phase of the cycle helped in reducing the side effects [16]. But because of its high price and side effects, 19 patients (20%) discontinued treatment.

**CONCLUSION**
This study has demonstrated that Centchroman therapy is found safe and cost effective . It helps in improving the quality of life by its high cure rate in comparison with Danazol and Tamoxifen.

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