



Centchroman - A Magical Pill or a Myth

Authors

**Natasha Thakur¹, Nadeem Ul Nazeer², Sahil Sandal³, Muzefer Ahmad Ahangar⁴,
Mohammed Omer Shah⁵, Mudasir Habib Shah⁶, Bilal Ahmed Wagay⁷, Rouf A Wani⁸**

^{1,3,4,5,6,7,8}Department of General and Minimally Invasive Surgery, Sher-i-Kashmir Institute of Medical Sciences, Soura, Srinagar, Kashmir, India-190011

²Department of Cardiovascular and Thoracic Surgery, Sher-i-Kashmir Institute of Medical Sciences, Soura, Srinagar, Kashmir, India-190011

Corresponding Author

Natasha Thakur, MBBS, MS

Department of General and Minimal Invasive Surgery, Sher-I-Kashmir Institute of Medical Sciences, Soura, Srinagar, Kashmir, India-190011

Email: doc_nats259@yahoo.co.in, Mob no 9419053202

Abstract

MASTALGIA is a common symptom experienced by most of the females and most common complaint encountered in outpatient department. Many agents have been tried but till now ideal treatment still awaits. Centchroman (ormeloxifene) is a selective estrogen receptor modulator.

Method: 56 Eligible patients of cyclic as well as non cyclic mastalgia were enrolled in our study to evaluate the efficacy of centchroman. Patients were treated with centchroman 30 mg daily for three months. Patients were followed at 4, 8, 12 weeks up to a period of 6 months. Patients were assessed using VAS score (visual analogue pain score) and breast pain chart.

Results: At 12 weeks, 87% women achieved reduction in pain score <3. Centchroman is an effective, safe, inexpensive and easily available drug for mastalgia. Except for 3 patients who had delay of menstruation 7-10 days.

Keywords: Mastalgia, Cyclic Mastalgia, Non Cyclic Mastalgia, Centchroman.

INTRODUCTION

The most prevalent breast disorder which makes women to attend clinic is breast pain or mastalgia. Mastalgia infact is the reason for 30-47 % of the referrals for clinical breast examination^(1,2). This disorder is broadly grouped into cyclic, non cyclic⁽³⁾ and extra mammary cause like trietze syndrome⁽⁴⁾. Cyclic mastalgia is related to menstrual cycles and it starts in luteal phase. The

symptoms of cyclic mastalgia include congestion of breasts, soreness and feeling of heaviness and tenderness^(5,6). Cyclic pain occurs in 70% of the female population. After exclusion of breast cancer and proper reassurance, only 15% of the patients will require drug treatment⁽⁷⁾. It may be severe enough to influence usual daily activities⁽⁸⁾. Various modalities like wearing a proper fitting and supportive bra⁽⁹⁾, heat/cold therapy, non

medical means like dietary measures like fat restrictions⁽¹⁰⁾ and avoidance of methylxanthines⁽¹¹⁾. Various drugs have been tried for mastalgia like evening primrose oil, danazol, tamoxifene, bromocriptine, topical non steroidal anti-inflammatory and recently centchroman. Centchroman [ORMILOXIFENE] is a selective estrogen receptor modulator⁽¹²⁾. It is primarily used as an oral contraceptive pill and is being distributed in India free of cost under National Family Welfare Programme.

PATIENTS AND METHODS

This study was conducted in Sher-i-kashmir Institute of Medical Science over a period of one year. 56 patients were selected, with mean age of 34.28 years.

All women with mastalgia having pain of VAS score >4 for more than 1 week were included in our study.

Exclusion Criteria:

1. Past history of breast cancer.
2. Family history of breast cancer. Pregnancy.
3. Patients of ovarian disorder and lactating mothers.

All women above 18 years of age presenting in our out patient department with complaints of mastalgia were chosen for the study. Initial clinical assessment was done by taking complete history, physical examination and were assessed by imaging. For females younger than 35 years, ultrasound was sufficient and in females more than 35 years, mammography was done. Along with ultrasound of breast, ultrasound of pelvis was done to exclude any ovarian pathology like polycystic ovaries, cervical hyperplasia. Patients were given centchroman 30 mg daily for 3 months. Patients were explained benefits of the medicine and side effects like scanty and delayed menstruations. Patients were instructed to maintain pain chart every day along with time of menses. The severity of mastalgia was assessed by visual analogue score (VAS) ranging from 0 to 10. 0 indicating no pain and 10 indicating very severe

pain. In case of severe mastalgia, patients were given NSAIDs. Patients were assessed at 4, 8, 12 week and again reassessed at 24 weeks and the response to therapy was assessed by VAS score. Patients were given centchroman for 3 months and treatment was stopped after completion of 3 months. Patients were followed for another 3 months and patients were reassessed. All data were entered and descriptive analysis was done by SPSS version 17 software. At the end of 1 month, 41 patients (73.21%) had responded and 15 patients (26.28%) had severe pain. At the end of 2 months, 46 patients (82.14%) had improvement and 10 patients (17.85%) continued to have pain. At the end of 3 months, 49 patients (87.5%) and 7 patients (12.5%) continued to have pain. There was significant pain relief in patients, both in cyclic and non cyclic groups. 73.21% in 1st month, 82.14% in 2nd month and 87.5% in 3rd month. Only 12.5% continued to have pain even after completion of treatment.

RESULTS

Table-1: Number of Patients

Type of Pain	No. Of Patients
Cyclical mastalgia	38
Non cyclical mastalgia	18

Table-2: (Result of three month therapy)

Follow up	VAS
1 Month	73%
2 Month	82%
3 Month	87%

Table-3: shows number of patients who achieved pain relief in both cyclical and non cyclical group

Time	Cyclic	Non cyclic
1 Month	30	17
2 Months	34	12
3 Months	37	12
6 Months	35	12

Table-4: shows response of pain using VAS score

Time	Cyclic (n=38)	Non cyclic (n=18)	No response
1 month	30	11	15
2 Month	34	12	10
3 Month	37	12	7
6 Month	35	12	9

Characterization of pain by evaluating the breast pain chart revealed that 38 patients had cyclic mastalgia and 18 patients had non cyclic mastalgia. Patients were assessed by using VAS score. At the end of 1st month, patients were assessed by using VAS score 41 patients (73.21%) responded and 15 patients (26.78%) had pain. At the end of 2nd month, 46 patients (82.14%) were symptomatically better and 10 patients (17.85%) still had pain.

At the end of 3rd month, 49 patients (87.5%) were symptom free and 7 patients (12.5%) continued to have pain. On comparing pain relief between cyclic and non cyclic, we found cyclic group patients responded better as compared to non cyclic. On follow up for 6 months, 47 patients (83.92%) were symptom free and 9 (16.07%) patients continued to have pain.

DISCUSSION

Painful breasts have become one of the most frequent reasons for consultation⁽¹³⁾. There is considerable discussion about selecting the best method for the primary management of breast pain⁽¹⁴⁾. Recently, Centchroman (Ormeloxifene-c30 H35NO3) a non-hormonal, non-steroidal oral contraceptive pill⁽¹⁵⁾ is being used in mastalgia. It is a SERM or SERMS which act on the estrogen receptor^(16,17). It has a weak estrogen agonistic activity in some tissues like bones and potent anti-estrogenic action in uterus and breast⁽¹⁸⁾. It is devoid of progestogenic, androgenic and antiandrogenic activity. In our study, the response with centchroman was 87.5% which is comparable to response noticed by Dhar A et al⁽¹²⁾ 12 at the end of 12 weeks. Tejawani PL et al⁽¹⁹⁾ noticed 100% response in their study of comparison between danazol and centchroman. Whereas 66% response was observed by Udaya Kumar Rajswaroob et al⁽²⁰⁾ in their study of effectiveness of centchroman on regression of mastalgia and fibroadenosis. Rathi J et al⁽²¹⁾ observed overall response rate of 88% at the end of 12th week and 85% at the end of 24 weeks and found that the drug was more effective with a

quick response in cyclic mastalgia than non cyclic mastalgia. This was also observed in our study. 80% response with regression of nodularity in three months was also noticed by Seema Khanna et al⁽²²⁾. In our study, 8 patients had menstrual irregularities, which were reversed after stopping medication. Menstrual irregularities were also noticed by Tejawani et al⁽¹⁹⁾, Ragswaroob et al⁽²⁰⁾, Kumar S et al⁽²³⁾ and Dhar A et al⁽¹²⁾.

CONCLUSION

Our study showed that response was good with centchroman as the drug is safe, inexpensive and can be safely used in patients with mastalgia. Indeed it is a magical pill in present time.

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