



CLINICAL STUDY OF MANAGEMENT OF CYCLIC MASTALGIA

Surgery

Dr. Archana Chaudhari

Senior Resident, GMC, Chatrapati Sambhajanagar.

Dr. Vinodkumar Jagdish Parmar*

Junior Resident, GMC, Chatrapati Sambhajanagar. *Corresponding Author

Dr. Syed Faiyaz Ali Majid Ali

Assistant Professor, GMC, Chatrapati Sambhajanagar.

Dr. Sarojini Jadhav

Professor and Head of Department, GMC, Chatrapati Sambhajanagar.

ABSTRACT

Mastalgia, or breast pain, is a common complaint that may affect up to 70% of women in their lifetime. Very few studies conducted in Maharashtra regarding study of cyclical mastalgia at tertiary care centre. The aim of this study was to evaluate the effect of different treatment modalities in management of Cyclic mastalgia. This was a prospective observational study. Total 110 eligible females were enrolled in study. There was no significant association between age of female with mastalgia & clinical presentation (p 0.348). (Table 3) But there was significant association between menstrual cycle & clinical presentation (p 0.031). Tab.Centchroman is the most effective treatment modality for cyclic mastalgia among all the options studied. However, we recommend advising patients to try non-pharmacological treatment modalities first. If the mastalgia persists, Tab.Centchroman is a better treatment option than topical Diclofenac gel, owing to its ease of administration and cost-effectiveness.

KEYWORDS

Cyclical mastalgia, tab Centchroman, topical Diclofenac

INTRODUCTION

Mastalgia, or breast pain, is a common complaint that may affect up to 70% of women in their lifetime.[1] It is not unusual for women to have 2–3 days of mild breast pain premenstrually but 8–30% of women report moderate to severe breast pain with duration of 5 or more days each month.[2] Fifteen percent of women who present to a breast clinic with Mastalgia will require treatment. Prevalence of mastalgia is highly variable ranging 41–79%. Approximately, 40–70% of cases of breast pain (BP) are caused by cyclical mastalgia (CM) and are related to hormonal cycling of estrogen, progesterin, and prolactin, while acyclical mastalgia (ACM) is more frequent or severe and interferes with daily activities and accounts for about 30% of breast pain.[3]

Breast pain is classified as cyclical mastalgia, non-cyclical mastalgia and nonspecific extra-mammary pain. Cyclical mastalgia is a breast pain that has clear relationship to the menstrual cycle. Non-cyclical mastalgia may not be necessarily associated with menstrual cycle, may be constant or intermittent and often occurs after the menopause. Nonspecific extra-mammary pain arises from the chest wall from other sources and is interpreted as having the cause within the breast.[4] The majority of those referred to a breast clinic require no more than exclusion of cancer and reassurance. But in 15% of the referred population, the severity of pain affects the patient's quality of life and requires drug treatment.[5]

Evaluation of pain can be done by a Visual Analogue Scale (VAS). It is a measurement instrument that tries to measure a characteristic or attitude that is believed to range across a continuum of values and cannot easily be directly measured. It is frequently used in epidemiologic and clinical research to measure the intensity or frequency of various symptoms.[6] VAS is usually a horizontal line, 10 cm in length, anchored by word descriptors at each end. The patient marks on the line below, the point that they feel represents their perception of pain. The VAS score is determined by measuring in millimeter from the left hand end of the line to the point that the patient marks. On this VAS, the 0 indicates no pain and 10 indicate very severe excruciating pain in the breast. Most mastalgia experts consider any pain of ≥ 3 on a VAS of 0 to 10 to be significantly severe to require therapy[7].

The incidence of benign breast disease is thought to exceed that of carcinoma breast by perhaps a factor often or more, with no reliable statistics available for the country. The reason for many referrals by general practitioners is anxiety and fear of breast cancer on the part of the patient, the parent or her doctor. It is therefore important not only to treat the symptoms but also to allay any fears that may exist. It is

imperative to emphasize that mastalgia does not imply any neoplastic process.[8]

Very few studies conducted in Maharashtra regarding study of cyclical mastalgia at tertiary care centre. The aim of this study was to evaluate the effect of different treatment modalities in management of Cyclic mastalgia.

METHODOLOGY-

This was a prospective observational study conducted at Government Medical College and Hospital among all females more than 18 years with breast pain during study period. The duration of study period was from Dec 2020 to Nov 2022. Approval was obtained prior to the start of the study from the Institutional Ethics Committee of Medical College. All female who give consent were included in the study.

Sample size was calculated With reference to study by Nirhale DS et al, reported that the proportion of cyclical mastalgia was 43.7 % [9]. About 110 eligible female with breast pain who willingly consented to participate were enrolled by systematic random sampling technique. Every 5th female with breast pain were enrolled in study.

Pre-designed, pretested semi-structured questionnaire was used for data collection. Study tool questionnaires included socio-demographic characteristics, medical history, past history, general examination & systematic examination. Pain was evaluated using visual analog scale. The evaluation of pain was done using a visual analog scale, prior to giving the treatment and after giving the treatment each week for the first month and thereafter monthly for the next 6 months. Three different treatment modalities were used to treat the patients like T. Centchroman, Diclofenac gel or with placebo. All patients divided in to three groups, Group A received T. Centchroman 30 mg alternate day (n=37), Group B received Topical NSAIDs Diclofenac 2% Tid (n=37), & Group C received nonpharmacological placebo treatment (n=36).

Statistical Analysis

Data was fed in master chart by using MS excel. Data was expressed as frequency and percentages, means, median, standard deviations and range in tabular and graphical format. Statistical comparison between two groups was made using the Chi-square test (categorical variables). p-values with two tailed. Statistical significance was set at $p = < 0.05$ as statistically significant and $p = < 0.01$ statistically highly significant. All calculations were made using the SPSS V26.0 trial version.

RESULTS:

During the study period total 110 female patients with mastalgia were

enrolled in the study, 47.27% belonged to age group of 26-33 years. About 45.45% of females were highly educated & 38.18% were employed. Majority of females belong to higher socio-economic class. About 70% females were married & 74.54% patients had regular menstrual cycle. (Table 1)

Table 2 shows most the females come to OPD with chief complain of pain in breast (70.9%) & others come pain with lump in breast (29.09%). Most of the females (52.72%) had bilateral involvement of breast. The most common final diagnosis was Fibroadenosis (74.54%). In our study we used three different modalities of treatment. About 37(33.63%) females received Tab. Centchroman (Group A),37(33.63%) received topical Diclofenac gel (Group B) & 36(32.72%) received placebo, a nonpharmacological treatment (Group C).

There was no significant association between age of female with mastalgia & clinical presentation (p 0.348). (Table 3) But there was significant association between menstrual cycle & clinical presentation (p 0.031). (Table 4)

The table 5 shows 66.32% response rate was observed in patients on T.Centchroman. Mean visual analog score at the beginning of the study was 6.42 and mean visual analog score at the end of 6 months period was 1.94 (p = 0.02). 59.62% response rate was observed in patients on non-pharmacological measures. Mean visual analog score at the beginning of the study was 5.62 and mean visual analog score at the end of 6 months period was 2.98 (p = 0.02).60.02% response rate was observed in patients on diclofenac gel. Mean visual analog score at the beginning of the study was 4.48 and mean visual analog score at the end of 6 months period was 2.97 (p = 0.02)

Table 1: Distribution Of Females According To Sociodemographic Profile

Parameters		Frequency	Percentages
Age groups	18-25	22	20
	26-33	52	42.27
	34-41	32	29.09
	42-50	4	3.63
Education	Primary	22	20
	Secondary	38	34.54
	Higher	50	45.45
Occupation	Housewife	13	11.81
	Labourer	9	8.18
	Farmer	14	12.72
	Employed	42	38.18
Socioeconomic Class	Shopkeeper	22	20
	Saleswomen	10	9.09
	Upper	35	31.81
	Upper Middle	27	24.54
	Middle	17	15.45
Marital Status	Lower Middle	18	16.36
	Lower	13	11.81
	Marrried	77	70
Menstrual History	Unmarried	33	30
	Regular	82	74.54
Parity	Irregular	28	24.45
	Nullipara	57	51.81
Treatment Modalities	Primipara	38	34.54
	Multipara	15	13.63

Table 2 : Distribution Of Females According To Clinical Profile

Clinical features	Pain	78	70.9
	Pain with Lump	32	29.09
Side of involvement	Right	22	20
	Left	30	27.27
	Bilateral	58	52.72
Final diagnosis	Fibro adenosis	82	74.54
	Fibroadenoma	12	10.9
	Mastitis	10	9.09
	Others	6	5.45
Treatment Modalities	Tab. centchroman	37	33.63
	Topical Diclofenac gel	37	33.63
	Placebo	36	32.72

Table 3: Association Between Age & Clinical Presentation Among Females With Mastalgia.

Clinical features	Pain	Pain with Lump	p Value	
Age groups	18-25	18 (81.81%)	4 (18.19%)	0.348
	26-33	32 (61.53%)	20 (38.47%)	
	34-41	26 (81.25%)	06 (18.75%)	
	42-50	02 (50%)	02 (50%)	

Table 4: Association Between Clinical Presentation & Menstrual History Among Females With Mastalgia.

Clinical presentation	Menstrual History		P Value
	Regular	Irregular	
Pain	50 (64.10%)	28 (35.89%)	0.031
Pain with Lump	28 (87.5%)	04 (12.5%)	

Table 5: Comparison Of Visual Analog Score According To The Treatment Given In Study

Follo up	VAS Score (Mean ±S.D.)			P Value
	Tab. Centchroman (n=37)	Topical Diclofenac gel (n=37)	Placebo (n=36)	
At 1 week	6.42±0.59	4.48±0.516	5.62±0.887	0.02
At 2 week	5.83±0.623	5.39±0.372	5.42±0.723	0.034
At 3 week	4.29±0.482	5.10±0.342	5.10±0.592	0.12
At 2 months	4.22±0.462	4.93±0.802	4.60±0.681	0.18
At 3 Months	3.42±0.403	4.20±0.562	4.74±0.872	0.52
At 4 Months	3.09±0.126	4.13±0.992	4.00±1.00	0.67
At 5 Months	2.43±1.182	3.25±1.542	3.37±1.437	0.37
At 6 Months	1.94±1.022	2.97±1.062	2.98±1.273	0.02
% of changes	66.325	60.02%	59.62%	

DISCUSSION:

The present study was conducted among females with mastalgia to evaluate the effect of different treatment modalities in management of Cyclic mastalgia. Majority of study participants were from 26-33 years age group. The similar findings was also found in study conducted by Nirhale DS & Geschickter [9,10]. In our study we found that most of the females were highly educated, employed & belong to higher socio-economic class. Also, in our study we found that most of the women were married. The similar finding was found in study conducted by Mansel RE et al. [11]. Majority of females, we found that had regular menstrual cycle & most of them were nullipara. Similar result was found in study conducted by Mansel RE et al. [11] & Tejwani PL et al [12].

Most the females had bilateral involvement of breast. Similar findings was found in study conducted by Mansel RE et al [11] & Guerriero S et al [13]. In our study, most of females were complaining of pain in breast followed by pain with lump in breast. Similar finding was found in study conducted by Nirhale DS et al [9]. The most common diagnosis among female in our study was fibroadenosis. Similar findings was found in study conducted by Nirhale DS et al [9], Geschiter [10] & Chowdhary RA et al [13]

In our study we found that, there was no association between age & clinical presentation but there was a significant association between clinical presentation & menstrual cycle. Simillar results was found in study conducted by Nirhale DS et al [9] & Kumar S et al [14]. In our study there was significant reduction in pain in breast after 6 month of treatment. Similar observations were noted by Colak T et al [15], found that the 80 % efficacy of non-steroidal anti-inflammatory drugs. The pain score prior to treatment was 7.13 and pain score after 6 months treatment was 1.26

CONCLUSION:

Based on our study results, we conclude that Tab.Centchroman is the most effective treatment modality for cyclic mastalgia among all the options studied. However, we recommend advising patients to try non-pharmacological treatment modalities first. If the cyclical mastalgia persists, Tab.Centchroman is a better treatment option than topical Diclogel, owing to its ease of administration and cost-effectiveness.

REFERENCES:

1. Arslan M, Küçükerdem HS, Can H, Tarcan E. Retrospective Analysis of Women with Only Mastalgia. J Breast Health. 2016;12(4):151-4.
2. Ader DN, South-Paul J, Adera T, DeusterPA. Cyclical mastalgia: prevalence and associated health and behavioral factors. J PsychosomObstetGynaecol. 2001;22(2):71-6.
3. Holland PA, Gateley CA. Drug therapy of mastalgia. What are the options? Drugs. 1994; 48(5):709-16.

4. Thakur N, Zargar B, Nazeer N, Parray F, Wani R. Mastalgia – Use Of Evening Primrose Oil In Treatment Of Mastalgia. *Int J Surg.* 2010;24(2):1-6.
5. Wang DY, Fentiman IS. Epidemiology and endocrinology of benign breast disease. *Breast Cancer Res Treat.* 1985;6(1):5-36.
6. Ader DN, Shriver CD. Cyclical mastalgia: prevalence and impact in an outpatient breast clinic sample. *J Am Coll Surg.* 1997;185(5):466-70.
7. Wewers ME, Lowe NK (1990) A critical review of visual analogue scales in the measurement of clinical phenomena. *Res Nurs Heal* 13:227–236.
8. Ndhuni A. The ABC of benign breast disease. *CME.* 2010;28(1):6-8
9. Nirhale DS, Dhende M, Shingade P, Chavan S, Sonawane T, Kulkarni G. A study on clinical profile and management of mastalgia. *Int Surg J* 2018;5:1889-93.
10. Geschickter CF. Mastodynia (Painful breasts) In: *diseases of the Breast, 2nd Edition* JB. Lippincott Co., Philadelphia; 1945:183-99.
11. Mansel RE, Dogliotti L. European multicentre trial of bromocriptine in cyclical mastalgia. *Lancet.* 1990; 335(8683):190-3.
12. Tejawani PL, Srivastava A, Nerkar H, Dhar A, Hari S, Thulkar S, Chumber S, Kumar S. Centchroman regresses mastalgia: a randomized comparison with danazol. *Indian J Surg.* 2011 Jun;73(3):199-205.
13. Chowdhury RA, Hasan SK, Masud JMD. Analysis of breast pain: a study of 110 cases. *J Medi.* 2009; 10(2):77-81.
14. Kumar S, Rai R, Das V, Dwivedi V, Kumar S, GGA. Visual analogue scale for assessing breast nodularity in non discrete lumpy breasts: the Lucknow Cardiff breast nodularity scale. *The Breast.* 2010;19(3):238-42.
15. Colak T, Ipek T, Kanik A. Efficacy of topical non-steroidal anti-inflammatory drugs in mastalgia treatment. *J Am Coll Surg.* 2003;196(4):525-30.