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A study on clinical profile and management of mastalgia

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ABSTRACT

Background: The aim of the present study is to observe the clinical profile and management of mastalgia. The objectives of the present study were to assess the clinical profile of breast diseases causing mastalgia, to study the response of mastalgia to the following three drugs: Danazol, Bromocriptine, topical non-steroidal anti-inflammatory drugs (topical diclofenac gel).

Methods: It was prospective type of study. Inclusion criteria: Patients of age group 15-50 years, all patients suspected or diagnosed for breast pathology with mastalgia. Exclusion criteria: immune-compromised patients, all patients undergoing surgical removal of breast lump, pregnant females. Evaluation of pain was done using 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.

Results: The clinical profile of mastalgia was as follows: fibroadenosis accounting for 37 (46.25%), followed by 10 (12.5%) cases of fibroadenoma, 08 (10%) cases of mastitis, 06 (7.5%) cases of breast abscess, 03 (3.75%) cases of duct ectasia, 02 (2.50%) cases of galactocoele, 02 (2.50%) cases of breast carcinoma and 12 (15%) cases of non-specific extra-mammary pathology. Patient's response rate to different drugs included in the study was: 64.8% to danazol, 56.9% to bromocriptine and 76.01% to topical diclofenac gel.

Conclusions: Cyclical mastalgia accounted for more proportion of patients than non-cyclical mastalgia. Common causes of mastalgia being fibroadenosis, followed by fibroadenoma, mastitis, breast abscess, duct ectasia, galactocoele, breast carcinoma and non-specific extra-mammary pathology. Danazol and bromocriptine are effective in treatment of mastalgia, though they show different side effect profiles and varying patient compliance.

Keywords: Bromocriptine, Cyclical mastalgia, Danazol, Mastalgia, Non-cyclical mastalgia, Topical non-steroidal anti-inflammatory drugs (topical diclofenac gel)

INTRODUCTION

Mastalgia, or breast pain, is a common complaint that may affect up to 70% of women in their lifetime. 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.³

Breast pain is classified as cyclical mastalgia, non-cyclical mastalgia and non-specific 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. Non-specific extramammary 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

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 emphasise that mastalgia does not imply any neoplastic process. There are many controversies regarding the type and method of treatment done for mastalgia. So a prospective study will be done to study and determine the commonest etiology of mastalgia and its response towards various treatment modalities, such as topical non-steoridal anti-inflammatory drugs, bromocriptine, and danazol.

METHODS

The study was conducted in the Department of General Surgery, Dr. D. Y. Patil Medical College, Hospital and Research Center Pimpri, Pune. The present is Prospective. Period of Study: May 2015 to October 2017. Period Required for Data Analysis: 6 months.

Inclusion Criteria

 Patients of age group 15-50 years were included, all patients suspected or diagnosed for breast pathology with mastalgia.

Exclusion Criteria

 All proven cases of malignancies, immunocompromised patients, all patients undergoing surgical removal of breast lump, pregnant females.

A detailed study of clinical history of all the breast pathologies causing mastalgia was studied.

Local clinical examination and systemic examination were evaluated according to the proforma. Pain was evaluated using visual analog scale.

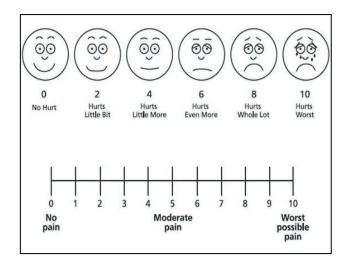


Figure 1: Visual analog scale to measure pain.

The patients who were studied were randomly categorized into 3 groups.

Table 1: Classification of patients based on the drug to be administered.

Groups	Drug	Dose	Duration
Group A	Danazol	200 mg bid	6 months
Group B:	Bromocriptine	2.5 mg bid	6 months
Group C:	Topical NSAIDs	2% tid	6 months

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.

RESULTS

In the present study, 42 patients (52.5%) out of 80 complaining of mastalgia were in the age group of 31-40 years, followed by 28 patients (35%) below the age of 30 years (Table 2).

Table 2: Age distribution of patients with mastalgia.

Age (years)	No. of cases	Percentage
≤30	28	35
31-40	42	52.50
>40	10	12.50
Total	80	100

In the present study, breast pain was the most common breast related symptom and accounted for 49 (61.25 %) patients (Table 3).

Table 3: Distribution of patients according to chief complaints.

Chief complaints	No. of cases	Percentage
Pain	49	61.25
Pain + lump	28	35.00
Pain + discharge	03	3.75
Total	80	100

In the present study, 35 patients (43.7 %) presented with cyclical mastalgia. Amongst these, 20 women (60%) belonged to the age group of 30-40 years (Table 4).

Table 4: Age distribution of patients with different types of mastalgia.

Age (years)	Cyclical type	Non- cyclical type	Non- specific type	Percentage
≤30	15	13	00	35
31-40	20	16	00	45.00
>40	00	04	12	20.00
Total	35	33	12	100

Various causes of mastalgia were observed: 37 (46.25%) due to fibroadenosis, 10 (12.5%) due to fibroadenoma, 08 (10%) due to mastitis, 06 (7.5%) due to breast abscess, 03 (3.75%) due to duct ectasia, 02 (2.50%) due to galactocoele, 02 (2.50%) due to breast carcinoma and 12 (15%) due to non-specific extra-mammary cause (Table 5).

Table 5: Quantification of patients according to diagnosis.

Final diagnosis	No. of cases	Percentage
Fibroadenosis	37	46.25
Fibroadenoma	10	12.50
Mastitis	08	10.00
Breast abscess	06	7.50
Duct ectasia	03	3.75
Galactocoele	02	2.50
Non-specific pain	12	15
Breast carcinoma	02	2.50
Total	80	100

In the present study, diclofenac gel showed the highest efficacy of approximately 76.01 %. Initial mean visual analog score of patients was 6.42 and at the end of 6 months period, mean visual analog score was 1.54 (p= 0.02) (Table 6).

In the present study, 23 patients with mastalgia were treated with danazol and 64.8~% showed efficient response of the drug in terms of reduction of breast pain and nodularity. Mean visual analog score in the beginning of treatment was 5.83 and mean visual analog score at the end of 6 months period was 2.05~(p=0.02) (Table 6). In the present study, 56.9~% response rate was observed in patients on bromocriptine. Mean visual analog score at the beginning of the study was 6.39~and mean visual analog score at the end of 6 months period was 2.75~(p=0.02) (Table 6).

Table 6: Comparison of visual analog score according the medications administered in study.

VAS score	Bromocr	Bromocriptine		Danazol		Diclofenac gel		P Value
VAS score	Mean	SD	Mean	SD	Mean	SD	F Value	P value
At 1 weeks	6.39	0.583	5.83	0.887	6.42	0.504	5.66	0.005
At 2 weeks	5.91	0.733	5.39	0.988	5.83	0.637	2.87	0.064
At 3 weeks	5.39	0.656	5.09	0.733	5.33	0.565	1.41	0.25
At 2 months	4.65	0.671	4.60	0.681	4.67	0.702	0.05	0.95
At 3 months	4.40	0.503	3.74	0.872	4.04	0.908	3.45	0.038
At 4 months	3.15	0.366	3.00	1.000	3.13	0.992	0.18	0.84
At 5 months	3.15	1.182	2.37	1.257	2.25	1.032	3.76	0.029
At 6 months	2.75	1.552	2.05	1.545	1.54	1.062	4.17	0.02
% change	56.96		64.84		76.01			

DISCUSSION

In the present study, 42 patients (52.5%) out of 80 complaining of mastalgia were in the age group of 31-40 years, followed by 28 patients (35%) below the age of 30 years. In a study of 375 cases conducted by Geschickter in 1945, he observed a mean age of 35 years with an average duration of pain of 21.5 months. In the present study, breast pain was the most common breast related

symptom and accounted for 49 (61.25 %) patients. It was observed in women in the age group of 23 to 45 years. Similar observations were noted by Guerriero S et al in a study conducted in 2010 wherein breast pain (48%) was the most common breast related complaint in women aged 25 to 44 years. In the present study, 35 patients (43.7 %) presented with cyclical mastalgia. Amongst these, 20 women (60%) belonged to the age group of 30-40 years. Similar findings were observed in a study of

400 cases conducted by Kumar S et al in 2010, where he observed cyclical mastalgia affecting 275 (68.8%) (p= 0.001) women in the age group of 31-40 years.¹⁰

In the present study, approximately 33 (41.2%) patients presented with non-cyclical mastalgia. These patients accounted for little more than one-third of all the cases in the study. In 2010, Lydia Cairncross observed that non-cyclical mastalgia accounts for nearly one-third cases of mastalgia. ¹¹

We observed various causes of mastalgia: 37 (46.25%) due to fibroadenosis, 10 (12.5%) due to fibroadenoma, 08 (10%) due to mastitis, 06 (7.5%) due to breast abscess, 03 (3.75%) due to duct ectasia, 02 (2.50%) due to galactocoele, 02 (2.50%) due to breast carcinoma and 12 (15%) due to non-specific extra-mammary cause.

In the present study, many patients complained of non-cyclical mastalgia. Amongst these, 11 (33.3 %) patients were of fibroadenosis, 07 (21.2 %) patients were of mastitis, 04 (12%) patients were of fibroadenoma, 06 (18 %) patients were of breast abscess and 02 (6 %) patients each of breast carcinoma and galactocoele. Similar observations were noted by Chowdhury RA et al in 2009, where he observed 51 (48.1%) patients were diagnosed as fibroadenosis, 16(15.1%) as non-specific mastalgia, 15 (14.2%) as breast abscess, 10(9.4%) as diseases of nipple, 02 (1.9%) as carcinoma of breast and 01 (0.94%) as galactocele. 12

In the present study, fibroadenosis was the most common benign breast disorder affecting women between 21 to 49 years age and accounted for 37 (46.2 %) cases. Similar findings were observed by Furlong AJ et al, Dixon JM et al and Rahal RMS et al in 1994, 1996 and 2005 respectively, wherein they found approximately 50% women diagnosed with fibroadenosis. ^{13,14,15}.

In the present study, 03 (3.75 %) patients presented with nipple discharge and were diagnosed as cases of duct ectasia. Similar findings were observed by Khanna AK et al, wherein he observed 03 (3.75 %) cases of nipple discharge. ¹⁶

In the present study, 2 out of 80 patients were diagnosed with breast carcinoma and presented with complaints of pain and lump. These patients accounted for 2.5 % of all cases. In 2006, Rosolowich V et al observed mastalgia as a presenting symptom of breast cancer in 5 – 18 % cases of breast cancer. The clinical profile of mastalgia In the present study includes the following causes: 37 (46.25%) due to fibroadenosis, 10 (12.5%) due to fibroadenoma, 08 (10%) due to mastitis, 06 (7.5%) due to breast abscess, 03 (3.75%) due to duct ectasia, 02 (2.50%) due to galactocoele, 02 (2.50%) due to breast carcinoma and 12 (15%) due to non-specific extra-mammary cause. In the present study, diclofenac gel showed the highest efficacy of approximately 76.01 %. Initial mean visual analog score of patients was 6.42 and at the end of 6 months

period, mean visual analog score was 1.54 (p = 0.02). Similar observations were noted by Colak T et al, where he observed 80 % efficacy of non-steroidal anti-inflammatory drugs in 108 women with mastalgia. The pain score prior to treatment was 7.13 and pain score after 6 months treatment was 1.26 (p = 0.0001). ¹⁸

It was observed that 15 out of 24 patients on topical diclofenac gel showed side effects; commonest being burning sensation on site of application in 8 (53.33%) patients, followed by tingling sensation on site of application in 05 (33.33%) and skin rash on site of application in 02 (13.33%) patients. It was observed that patients on topical diclofenac gel showed good compliance with mean duration of 6 months use (p = 0.13).

In the present study, 23 patients with mastalgia were treated with danazol and 64.8~% showed efficient response of the drug in terms of reduction of breast pain and nodularity. Mean visual analog score in the beginning of treatment was 5.83 and mean visual analog score at the end of 6 months period was 2.05~(p=0.02). Similar results were observed in a study by Greenblatt RB et al, wherein 130~(70~%) patients showed elimination of breast nodularity at daily doses of 100-400~mg danazol102. Parallel observations were noted by Kontostolis E et al. 19

In the present study, 12 out 15 patients with cyclical breast pain showed satisfactory response with danazol, accounting for 80 % cases. Similar findings were observed by Doberl A et al in 30 women with breast pain, where significant reduction in breast pain was noted (p = less than 0.005) and it was concluded that danazol can be efficiently used for cyclical breast pain108. Parallel observations were also noted by O'Brien PMS et al.²⁰

We observed drug induced side effects in 19 out of 23 patients treated with danazol. Amongst which, acne accounting for 10 (52.6%), muscle cramps accounting for 05 (26.32%) and weight gain accounting for 04 (21.05%) patients. In 1979, Baker HW et al observed weight gain as a common side effect in 6 of 23 patients (26.08%) on danazol use. In the present study, 4 of 23 (17.3%) patients showed poor compliance with danazol and lost follow up. In 1979, Humphrey LJ et al, observed a 9% dropout rate in patients with fibrocystic breast disease who were administered danazol at 100 mg daily dose. 22

In the present study, 56.9 % response rate was observed in patients on bromocriptine. Mean visual analog score at the beginning of the study was 6.39 and mean visual analog score at the end of 6 months period was 2.75 (p = 0.02). In 2007, Srivastava A et al observed 88% response to bromocriptine (p = less than 0.00001)117. About 10 of 23 patients (43.4 %) presented with cyclical mastalgia initially and showed satisfactory drug response with bromocriptine. Nazli K et al observed an absolute reduction of 40% in mean linear analog scores for pain. 23

In the present study, side effects of bromocriptine were dizziness in 02 (11.1 %) patients, headache in 07 (38.8 %) patients and nausea in 09 (50 %) patients. Similar observations were noted by Mansel RE et al in 1990, where he noted nausea (32%) and dizziness (12%) as side effects of bromocriptine. 24 In the present study, 03 of 23 (13.04%) patients showed poor compliance with bromocriptine and lost follow up. The patients on bromocriptine showed mean duration of 5.3 months use (p = 0.13). In the present study, the response of mastalgia to danazol was 64.8%, to bromocriptine was 56.9% and to topical non-steroidal anti-inflammatory drug (diclofenac gel) was 76.01%.

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