



ORIGINAL ARTICLE

Clinical Response to Different Medical Treatment Options for Mastalgia in Fibrocystic Breast Disease among Women at a Tertiary Care Hospital in Dhaka City

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Abstract

Background: Various types of medical management are given for mastalgia in fibrocystic breast disease. **Objective:** The aim of this study was to compare the effects of different commonly used medical management options of mastalgia of fibrocystic breast disease on the quality of life of the respondents and their side effects as well. **Methods:** This prospective longitudinal study was carried out in Out-patients Department of General Surgery, Bangladesh Institute of Research and Rehabilitation in Diabetes, Endocrine and Metabolic Disorders (BIRDEM) General Hospital, Dhaka, Bangladesh from July 2018 to June 2019. The patients with fibrocystic breast disease were selected according to the eligibility criteria and are allocated to two groups by alternative random selection. In non-pharmacological treatments receiving group, lifestyle modification advices along with Evening Primrose Oil were given. On the other hand, in pharmacological treatment receiving group, Bromocriptine and Danazole were given according to some selection criteria of the patients. Response of treatments to each group & side effects were determined at one month, three months and six months follow up respectively. **Results:** A total number of 45 patients were recruited for this study. Majority of them presented with cyclical mastalgia (57.78%), bilateral mastalgia (60%) and mastalgia with lumpiness (44.4%). Among the patients who received non-pharmacological treatment, mastalgia improved in 34.78% cases and patients received pharmacological treatment, mastalgia improved in 72.73% cases. Different domains of quality of life were improved significantly in patients who received pharmacological treatment. **Conclusion:** In conclusion pharmacological management by Danazol or Bromocriptine has well tolerated to the patients. [Journal of Current and Advance Medical Research, July 2021;8(2):95-99]

Keywords: Fibrocystic breast disease; mastalgia; EPO; danazol; bromocriptin; quality of life

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Introduction

Fibrocystic breast disease (FBD) is the most common type of benign breast disease¹ and mastalgia is the most common symptom of FBD². It represents a spectrum of clinical, radiological and histological findings of the breast in both asymptomatic and symptomatic women. Mastalgia causes concern and fear of breast cancer and has negative effects on quality of life³. Mastalgia caused by fibrocystic breast disease is treated by breast specialists as well as by those not specialized in breast diseases⁴. Unfortunately, these patients are treated inappropriately for prolonged duration with non-pharmacological management by Evening Primrose Oil^{2,5} in a fear of more side effects of pharmacological managements by certain drugs⁶.

Inappropriate selection of non-pharmacological treatment as a first line management option, sometimes creates financial burden and unchanged or recurrence of clinical symptoms⁷. Recent population based and breast clinic-based studies suggest that up to 70% of women experience breast pain in their lifetime⁸. Moreover, 10% of symptomatic participants had suffered breast pain for over half their lives. Of the symptomatic participants, 41% and 35% reported breast pain affecting the quality of life⁹. Fifteen percent of women who present to a breast clinic with mastalgia will require treatment^{8,9}.

Non pharmacological options of medical managements includes some life style modifications (LSM) like- an appropriately fitting and supportive bra, avoidance of caffeine drinks, reduction of dietary fat, increase fiber rich diet, physical exercise to reduce weight and relaxation training are said to be helpful for the treatment of mastalgia¹⁰ and some nutritional supplementations like oil of evening primrose (EPO) will help more than half of these women^{5,10,11}. For those with intractable symptoms, Pharmacological options of medical management like- an anti-gonadotropin, Danazol⁶, or a prolactin inhibitor like bromocriptine⁵, may be tried. Very rarely, it is necessary to prescribe an anti-estrogen, for example tamoxifen^{12,13}, or a luteinizing hormone-releasing hormone (LHRH) agonist to deprive the breast epithelium of estrogenic drive. Surgical interventions have a limited role in the management of mastalgia⁵ but last-resort options for unresponsive and severe debilitating breast-pain include mastectomy with reconstruction¹⁴. The aim of this present study was to assess the responses of various medical treatment options of mastalgia of

FBD on women's quality of life as well as side effects of used medications.

Methodology

It was a Prospective longitudinal study carried out in Outpatient department (OPD) of General Surgery, BIRDEM General Hospital, Dhaka, from July 2018 to June 2019. The patients with fibrocystic breast disease (FBD) presented in OPD of BIRDEM General Hospital, Dhaka, Bangladesh were selected as study population. The inclusion criteria were women of reproductive age group and patients diagnosed as fibrocystic breast disease by clinical, radiological or cytological examinations within the study period. Patients with suspected breast lesion or diagnosed breast malignancy, pregnant, lactating women and who were planning to have pregnancy in near future, history of any breast surgery or having congenital disability of breast were excluded from this study. A thorough history of each patient was obtained and careful physical examination carried out of each patient. Hormonal assay and USG of both breasts were done in every patient but Mammography and FNAC were done only in suspected cases to exclude FBD and occult breast carcinomas, particularly in patient having family history of breast diseases. Patients were allocated to two groups by alternative random selection (first one to non-pharmacological and second one to pharmacological, third to again non-pharmacological treatment receiving group and so on. Non-pharmacological treatments receiving group were given life style modification (LSM) advices along with Evening Primrose Oil (EPO). The LSM advices were wearing a supportive bra, exercise to reduce weight, reduction of mental stress by relaxation therapy, some dietary advices such as reduction of fat and caffeine intake, increase dietary fiber intake, etc. Evening Primrose Oil (EPO) was given orally in a dose of 1000mg thrice daily. In pharmacological treatment receiving group Bromocriptine and Danazole were given according to some selection criteria of the patients. Bromocriptine was given orally in a dose of 2.5mg twice daily, in those patient with increased prolactin level, having no known hypersensitivity to it, not taking any anticonvulsant, not having uncontrolled diabetes, severe ischemic heart disease or migraine. On the other hand, Danazole was given orally in a dose of 100mg twice daily in patients with normal prolactin level, hyperestrogenaemia, patients with no undiagnosed genital bleeding, previous thromboembolic disorders or markedly impaired hepatic, renal or cardiac functions. In both groups oral analgesics were given according to the severity of mastalgia. Acetaminophen was given 500mg

thrice daily for VAS 2-4 and Ibuprofen was given 200mg twice daily for VAS ≥ 6 in initial visit for one week to alleviate the severity of pain in both groups. Patients were advised not to take any analgesic after initial one week and report if the pain became intolerable. Response to each group of treatments, side effects & compliance of the patient were determined at 1 month, 3 months and 6 months follow up respectively. Mastalgia was measured by VAS score and QOL were calculated by modified WHO-QOL scoring (field trial version) in each follow up. Any side effects, willingness to continue the treatment were also asked to every patient in each follow up. No treatment was changed before 3 months of therapy, no matter what the response was. This study focused simply on the comparison of the two groups of medical treatments of mastalgia and their responses of QOL at beginning and after 6 months of treatment. Ethical clearance for this thesis work was taken from the Institutional Review Board (IRB) of BIRDEM General Hospital (No. BIRDEM /IRB/2017 /78) on 21 June, 2017. Informed Written Consents were taken from every patient.

Results

This was a Prospective type of longitudinal study conducted in OPD of BIRDEM General Hospital, Dhaka, Bangladesh. Total number of respondents

were 45. Highest respondents of our study were aged between 31 to 35 years (33.3%) and no respondents were aged between 45 to 50 years (0%). Mean age of the respondents were 30.24±6.93 years of SD (Table 1).

Table 1: Age Distribution among Respondents (n= 45)

Age Group	Frequency	Percent
16 to 20 years	4	8.9
21 to 25 years	10	22.2
26 to 30 years	11	24.4
31 to 35 years	15	33.3
36 to 40 years	3	6.7
41 to 45 years	2	4.4
46 to 50 years	0	0.0
Total	45	100.0

In pharmacological treatment received group 40.91% respondents treated with Danazole and 59.09% treated with Bromocriptine. After 6 months follow up, 72.73% had pain improvement in pharmacologically treated group and 34.78% had pain improvement in non-pharmacological group. Significant difference had been found between both groups. Here VAS 0-2 was considered as pain improvement and VAS 4 and above was considered as non-improvement of pain (Table 2).

Table 2: Distribution of the Respondents by 6 months follow up of non-pharmacological and Pharmacological Treatment using QOL parameters

Facets Incorporated Within Domains	Non pharmacological (n=23)		Pharmacological (n=22)		P value
	Improved	Not Improved	Improved	Not Improved	
Domains of QOL					
• Pain	8(34.8%)	15(65.2%)	16(72.7%)	6(27.3%)	*0.006
• Physical health	9(39.1%)	14(60.9%)	16(72.7%)	6(27.3%)	*0.008
Physical domain					
• Energy & Fatigue	8(34.8%)	15(65.2%)	15(68.2%)	7(31.8%)	*0.001
• Sleep & Rest	10(43.5%)	13(56.5%)	17(77.3%)	5(22.7%)	*0.05
• Self esteem	7(30.4%)	16(69.6%)	14(63.6%)	8(36.4%)	*0.031
Psychological domain					
• Concentration/ Attention	9(39.1%)	14(60.9%)	13(59.1%)	9(40.9%)	*0.002
• Negative feeling	6(26.1%)	17(73.9%)	12(54.5%)	10(45.5%)	*0.003
Social Relationship					
• Personal relationship	8(34.8%)	15(65.2%)	12(54.5%)	10(45.5%)	*0.151
• Sexual life	7(30.4%)	16(69.6%)	13(59.1%)	9(40.9%)	*0.08

*P value was determined by Chi-square test; Negative feeling=Anxiety, Depression

Table 3: Distribution of side effects of different Pharmacological and non-pharmacological treatment options

Adverse Effect	Frequency	Percent
Danazole		
Weight gain	6	13.3
Menstrual irregularity	7	15.6
Headache	5	11.1
Nausea	2	4.4
Acne	1	2.2
Non specific	4	8.9
Bromocriptine		
Headache	5	11.1
Nausea	2	4.4
Dyspepsia	2	4.4
Non specific	3	6.7
Evening Primrose Oil (EPO)		
Bloating	3	6.7
Headache	1	(.2

Discussion

Mastalgia with or without breast lump in FBD is common complaint among the patients and a cause of significant anxiety and fear of female breast cancer in Bangladesh as well as all over the world. In this study maximum respondents were age between 31 to 35 years (33.3%). The mean age of the respondents were 30.24±6.93 years of SD. Similar observations were found in some previous studies by Scurr et al⁹ and in a recent study done by Godazandeh et al¹⁵.

In this study 51.1% respondents underwent non-pharmacological treatment by LSM and EPO and 48.9% underwent pharmacological treatment, where 40.91% respondents treated with Danazole and 59.09% treated with Bromocriptine depending on the selection criteria.

In this study quality of life (QOL) in non-pharmacological treatment receiving group- in physical domain: pain 34.78%, physical health 39.13%, energy and fatigue 34.78% and sleep and rest 43.48% had improvement. In psychological domain: 30.43% had improvement of self-esteem, 39.13 % had improvement in concentration/attention and 26.09 % had improvement in negative feeling. In social relationship domain: in personal relationship 34.78% and in sexual life 30.63% had improvement. Beside in pharmacological treatment receiving group in physical domain: pain 72.73%, physical health 72.72%, energy and fatigue 68.18% and sleep and rest 77.27% had improvement. In

psychological domain: in self-esteem 63.64%, concentration/attention 59.09% and 54.55% negative feeling had improvement. In social domain: 54.55% personal relationship and 59.09% sexual life had improvement. In all domains improvements were significantly higher in pharmacological group.

Similar observation was seen in a previous study by Rajswaroob et al¹⁷ where he showed drug treatment was significantly effective for mastalgia. Ganz et al²⁰ observed mood and emotional functioning were same among all patients, with no differences by type of medical treatment received which is abit differ from our observation.

In this study majority of side effects occurred due to Danazole. Chronologically they are menstrual irregularity (15.6%), weight gain (13.3%), headache (11.1%), nausea (4.4%), acne (2.2%) and nonspecific side effects (8.9%). Beside headache (11.1%), nausea (4.4%), dyspepsia (4.4%) and nonspecific side effects (6.7%) due to Bromocriptine. Whereas only 6.7% had bloating and 2.2% had headache due to Evening Primrose oil (EPO). Here a single patient sometimes complained of multiple side effects. Almost similar observation was seen in some previous study by Rajswaroob et al¹⁷ and Neogi et al²¹ and Nirhale et al⁸.

There are some limitations of this study. This study was performed in a single tertiary care hospital among small available population size.

Conclusion

In this study, It has been found pharmacological managements by Danazole or Bromocriptine in precisely selected group of patients were well tolerated and a dramatic improvement was observed in overall quality of life of our patients. Despite of having various side effects of different pharmacological managements of mastalgia, it has been recommended timely use of them in the precisely selected patients of fibrocystic breast disease can help in reduction of their sufferings, cost of prolonged treatments by improving the quality of life in a relatively shorter period of time. Further large study is recommended involving multiple centers and long term follow up.

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