



Original Article

Effects of Evening Primrose Oil on Fibrocystic Breast Disease

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Abstract:

Introduction: As the term implies, fibrocystic breast tissue can feel *fibrous* and *cystic*. Estrogen, progesterone and prolactin hormones directly affect the breast tissues by causing cells to grow and multiply. There are multiple modalities of treatment but no one is widely accepted. Evening primrose oil is an excellent source of the essential fatty acid, which may reduce swelling & pain of fibrocystic disease.

Methods: Total 50 cases of clinically diagnosed fibrocystic breast disease were enrolled for study during August 2017 to August 2018. Sample was selected by purposive sampling technique. Data were collected from the patients and/or informant and recorded in structured case record form. Clinical examination and relevant investigations were done meticulously. At the first visit patients were treated by evening primrose oil. Then subsequent follow up conducted after 2 months and after 4 months of primary treatment to observe the effectiveness. Quantitative data expressed as mean and standard deviation and qualitative data as frequency and percentage.

Result: Most common symptom was lumpiness and pain in the breast (76.0% & 46.0% respectively). Other manifestations were breast lump in 24.0%, relation with cycle in 88.0% of patients. At the first follow-up (2nd month), lumpiness in the breast, localize swelling and tenderness was improved (52.0%, 70.0% & 48.0% respectively), but breast lump remained unchanged in all patients. At the second follow-up (4th month) significant improvement occurred. Lumpiness in the breast present in 36.0% patients, pain in the breast in 22.0%, localize swelling in 48.0% and tenderness in 30.0% of patients. Mean verbal pain score at baseline was 5.3, following treatment pain was resolved/ decreased. At 2nd month VAS score was 3.8 and at 4th month VAS score was 3.1. Clinical improvements were subjectively assessed by the patients after completing of the treatment. Subjective evaluation or patient satisfaction corresponded to 76.0% improvement.

Conclusion: In this study our experience showed that evening primrose oil can be prescribed at fibrocystic breast disease patients, as this shows high rate to relief of symptoms.

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Background

Fibrocystic change of the breast is a nonspecific term, commonly understood as a continuum of physiologic changes that expand to the pathologic spectrum. It is a condition characterized by “lumpy” breasts, associated with pain and tenderness that fluctuate with the menstrual cycle¹. Fibrocystic changes of the breast are common and should not be considered a disease. These changes are sometimes asymptomatic; however, when painful, patients would

seek medical advice. Lifestyle changes and the avoidance of certain dietary elements as well as the use of some non-pharmacological agents have shown some beneficiary effects². Clinically, it is a condition in which there are palpable lumps in the breast, usually associated with pain and tenderness, that fluctuates with the menstrual cycle and that becomes progressively worse until menopause³. This group of conditions is very common in younger women, occurring in about 20% of premenopausal females. Both breasts become tender or painful and lumpy, and the symptoms vary at different times in the menstrual cycle⁴.

The estimated incidence rate of fibrocystic changes increases with age, The peak incidence of symptoms occurs in women in the third and fourth decades of life, when the degree of diffuse palpable nodularity in the breast may increase^{5,6}. There is a higher prevalence of cysts as women approach menopause. Histologic evidence from autopsy studies finds fibrocystic changes in 54% of clinically normal breasts⁷.

Histologically, lesions of fibrocystic breast disease are of epithelial origin. Microscopically, they are usually micro- and macrocysts which may (or may not) be associated with apocrine epithelium, epitheliosis, adenosis, papillomatosis, and/or solitary and multiple papillomas⁸. Briefly, cysts are fluid-filled structures that are round-to-ovoid in shape and that vary in size from microscopic to grossly evident. Gross cysts⁹, are derived from the terminal ductal lobular unit and are large enough to produce palpable masses. The epithelium usually consists of an inner epithelial layer and an outer myoepithelial layer. Cysts can be associated with metaplasia, or hyperplasia, which can produce epitheliosis and adenosis.

Most women with fibrocystic changes and no symptoms do not need treatment, but closer follow-up may be advised. There is no widely accepted treatment or prevention strategy for fibrocystic condition. When treatment of symptoms is necessary it follows the same strategies as treatment for cyclical breast pain. Same vitamins and minerals can be

helpful in reducing and preventing breast cysts: vitamin A, vitamin E & iodine¹⁰. Evening primrose oil (EPO) is an essential fatty acid used empirically by many women to reduce cyclical mastalgia. EPO is a rich source of essential fatty acid and contains 7-14% gamma linolenic acid (GLA). Its mechanism of action is thought to involve inhibition of prostaglandin that potentially contributes to breast pain. Dietary GLA is metabolized to di-homo-gamma linolenic acid (DGLA), which can inhibit synthesis of arachidonic acid metabolites and exert an anti-inflammatory effect¹¹. Evening primrose oil is generally well tolerated, with reported minor adverse effects, including gastrointestinal upset and headaches. Commercial preparations of EPO are available in capsule or liquid form¹².

Materials & Methods

This was a prospective observational study conducted at the Department of Surgery, Faridpur Medical College Hospital, Faridpur. Patients diagnosed as cases of fibrocystic breast disease were included in this study. Patients with associated inflammatory breast conditions like breast abscess, mastitis were excluded from the study. Patients with pregnancies, patients already taking primrose oil, taking hormonal modulating drugs like danazol/bromocriptine, having associated fibroadenoma, or having hyper-prolactinamia also excluded from this study. Total 50 cases of clinically diagnosed fibrocystic breast disease were enrolled for study after fulfillment of selection criteria. Sample was selected by purposive sampling technique. Data were collected from the patients and/or informant and recorded in structured case record form. Clinical examinations and relevant investigations were done meticulously. At the first visit patients were treated by evening primrose oil. Then subsequent follow up conducted after 2 months and after 4 months of primary treatment to observe the effectiveness. Quantitative data expressed as mean and standard deviation and qualitative data as frequency and percentage. Comparison was done by tabulation and graphical presentation in the form of tables.

Result:

In this study maximum numbers of patients (44.0%) were between 31-40 years age group, mean±SD age was 34.7±10.2 years. Age distribution resembles normal distribution where the numbers of younger aged patients were high in contrast to elderly age groups. About 70% patient's age was <50 years. (Table I)

Table I : Demographic characteristics of the respondents. (n=50)

Variables	Frequency	Percentage	p value
Age			
<30 yr	13	26.0	0.503
31-40	22	44.0	
41-50	10	20.0	
>50	5	10.0	
Education status			
Illiterate	13	26.0	0.217
Primary class	22	44.0	
SSC	9	18.0	
HSC	6	12.0	
Graduate	0	0	
Residence			
Rural	19	38.0	
Urban	24	48.0	
Sub-urban/slum	27	14.0	
Occupation			
Service holder	8	16.0	
Day labourer	15	30.0	
House wife	23	46.0	
Business	4	8.0	

Most common symptom was lumpiness in the breast, pain in the breast(76.0% & 46.0% respectively). (Table II). Other manifestations were breast lump in 24.0%, relation with cycle in 88.0% of patients. (Table III)

Table II : Distribution of respondents by clinical presentation (n=50)

Clinical presentation	Frequency	Percentage (%)
Lumpiness in the breast	38	76.0
Breast lump	12	24.0
Pain in the breast	23	46.0
Discharge from the nipple	5	10.0
Relation With cycle	44	88.0
Multiple responses		

Table III: Distribution of respondents by clinical examination findings (n=50)

Clinical Findings	Frequency	Percentage (%)
Localize swelling	27	54.0
Fluctuation test	2	4.0
Peau d'orange	0	0
Redness	0	0
Tenderness	32	64.0
Ulceration	0	0
Multiple responses		

USG findings showed focal areas of thickening of the parenchyma with patchy increase in echogenicity in 35(70.0%) of patients, discrete single cysts or clusters of small cysts in 12(24.0%) of patients and fibroglandular tissue in the area of a palpable nodule was in 9 patients.

After treatment with evening primrose oil, symptomatic improvement/ deterioration was observed at different follow-up time. At 1st follow-up (2nd month), lumpiness in the breast, localize swelling and tenderness was improved (52.0%, 70.0% & 48.0% respectively), but breast lump was unchanged in all patients. At 2nd follow-up (4th month later) significant improvement occurred. Lumpiness in the breast present in 36.0% patients pain in the breast in 22.0%, localize swelling in 48.0% and tenderness in 30.0% of patients. Mean verbal pain score at baseline was 5.3, following treatment pain was resolved/ decreased. At 2nd month VAS score was 3.8 and at 4th month VAS score was 3.1. Clinical improvements were subjectively assessed by the patients after completing of the treatment. (Table IV).

Table IV : Assessment of major symptomatic improvement/ deterioration at different follow-up time (n=50)

Follow up time		Frequency	Percentage (%)
At 2 nd month	Lumpiness in the breast	26	52.0
	Breast lump	12	24.0
	Pain in the breast	18	36.0
	Localize swelling	35	70.0
	Tenderness	24	48.0
	Lumpiness in the breast	18	36.0
At 4 th month	Breast lump	7	14.0
	Pain in the breast	11	22.0
	Localize swelling	24	48.0
	Tenderness	15	30.0

The results of the subjective evaluations were as follows: “improved” – if symptoms are relieved and functional recovery is better than previous condition; “not improved” – if symptoms is not relieved or status is similar before and after treatment. Subjective evaluation or patient satisfaction corresponded to 76.0% improvement. Evening primrose oil is valuable treatment option for fibrocystic Breast Disease in terms of clinical & imaging improvement. P value is 0.00371 and result is significant at $p < 0.05$. (p-value reached from chi-square test).

Discussion

Fibrocystic changes (FCCs) constitute the most frequent benign disorder of the breast. Such changes generally affect premenopausal women between 20 and 50 years of age¹³. In this study maximum numbers of patients (44.0%) were between 31-40 years age group, mean \pm SD age was 34.7 ± 10.2 years. Age distribution resembles normal distribution where the numbers of younger aged patients were high in contrast to elderly age groups. About 70% patient's age was <50 years.

The signs and symptoms of fibrocystic breast disease include: one or more lumps in breasts, which may or may not be painful, nipple discharge, breast tenderness or sensitivity¹⁴. Fibrocystic breast disease is a condition causing symptoms like tenderness and discomfort of the breasts normally during premenstrual periods, lumpy masses in the breasts which are often asymptomatic and sudden appearance and disappearance of benign masses in the breasts, pain and discomfort under the arms¹⁵. In this study most

common symptom was lumpiness in the breast, pain in the breast (76.0% & 46.0% respectively). Other manifestations were breast lump in 24.0%, relation with cycle in 88.0% of patients.

Evening primrose oil (EPO) has become a medically accepted treatment for fibrocystic breast disease in the United States and Europe¹⁶. Fatty acid metabolism is known to be disturbed in women with cyclical mastitis. In open studies performed at the Cardiff Mastalgia Clinic in the Britain, EPO has been found to produce positive effects in 44% of women with cyclical mastalgia¹⁶. According to the same researchers, this was about the same benefit as seen with a prescription drug bromocriptine, but danazol was somewhat more effective (70% response rate). In a double-blind placebo-controlled study, 73 patients with mastalgia randomly received evening primrose oil 3 g/day or placebo for 3 months. Over the course of the study, discomfort was significantly reduced in women with either cyclical or noncyclical mastalgia, while no significant improvement was seen in the control. Nodularity improved only in the cyclic group¹⁶.

After treatment with evening primrose oil, symptomatic improvement/ deterioration was observed at different follow-up time. At 1st follow-up (2nd month), lumpiness in the breast, localize swelling and tenderness was improved (52.0%, 70.0% & 48.0% respectively), but breast lump was stand still in all patients. At 2nd follow-up (4th month) significant improvement occurred. Lumpiness in the breast present in 36.0% patients pain in the breast in 22.0%, localize swelling in 48.0% and tenderness in 30.0% of patients. Mean verbal pain

score at baseline was 5.3; following treatment pain was resolved/ decreased. At 2nd month VAS score was 3.8 and at 4th month VAS score was 3.1. Clinical improvements were subjectively assessed by the patients after completing of the treatment. Subjective evaluation or patient satisfaction corresponded to 76.0% improvement.

Conclusion

Fibrocystic breast conditions is the most common cause of “benign breast lump”. Present study demonstrated that evening primrose oil is a effective treatment option for relief of pain with other symptoms in fibrocystic breast disease. Primrose oil is a non harmful, cheap and easily available popular medicine used for fibrocystic breast disease with the intention of relieving symptoms. So, it can be used for treatment of fibrocystic breast disease.

References

1. Sugg S, Lizarraga I, Fu S. Fibrocystic breasts. Downloaded from: <https://bestpractice.bmj.com/topics/en-us/1003>. Retrieved on August 2018.
2. Murshid K. A Review of Mastalgia in Patients with Fibrocystic Breast Changes and the Non-Surgical Treatment Options. *Journal of Taibah University Medical Sciences* 2011; 6(1):1-18.
3. Goehring C and Morabia A. Epidemiology of Benign Breast Disease, with Special Attention to Histologic Types. *Epidemiologic Reviews* 1997; 19(2):310-326.
4. Fibrocystic Breast Disease: Overview. Downloaded from: <https://www.diagnose-me.com/symptoms-of/fibrocystic-breast-disease.php>. Retrieved on August 2018.
5. Goehring C, Morabia A. Fibrocystic breasts: Epidemiology. *BMJ Publishing Group Ltd* 2018: 1-2
6. Goehring C, Morabia A. Epidemiology of benign breast disease, with special attention to histologic types. *Epidemiol Rev.* 1997; 19:310-327.
7. Sarnelli R, Squartini F. Fibrocystic condition and “at risk” lesions in asymptomatic breasts: a morphologic study of postmenopausal women. *Clin Exp Obstet Gynecol.* 1991; 18:271-279
8. Schnitt SJ, Conolly JL. Benign breast disorders. In: Harris JR, Hellmann S, Henderson IC, et al., eds. *Breast diseases*. Philadelphia, PA: Lippincott-Raven, 1996: 15-30.
9. Haagensen CD. *Diseases of the breast*. 3rd ed. Philadelphia: Saunders, 1986: 1-168.
10. Greene W. Fibrocystic Breast Disease. Downloaded from: <https://www.dcnutrition.com/health-problems/fibrocystic-breast-diseas>. Retrieved on July 2018.
11. Pruthi S, Wahner-Roedler DL, Torkelson CJ, Cha SS, Thicke LS, Hazelton JH, Bauer BA. Vitamin E and evening primrose oil for management of cyclical mastalgia: a randomized pilot study. *Altern Med Rev* 2010; 15(1):59-67.
12. Bayles B, Usatine R. Evening Primrose Oil. *Am Fam Physician.* 2009; 80(12):1405-1408.
13. Guray M, Aysegul A. Benign Breast Diseases: Classification, Diagnosis, and Management. *The Oncologist* 2006; 11:435–449.
14. Fibrocystic Breast Disease: Treatment, Procedure, Cost and Side Effects. Downloaded from: <https://www.lybrate.com/topic/fibrocystic-breast-disease>. Retrieved on August 2018.
15. What is Evening Primrose Oil? Downloaded from: <http://www.menopausers.com/>. Retrieved on August 2018.
16. Premenstrual Breast Pain & Irritability: Plant Estrogens. (Fact sheet).