

Assessment of the Effect of Evening Primrose Oil Therapy in the Management of Breast Fibroadenoma

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ABSTRACT

Objective: To assess the effect of evening primrose oil usage on reduction in size of breast fibroadenoma in Pakistani female population.

Study Design: Experimental study.

Place and Duration of Study: This study was conducted at the Quasi experimental study conducted at Creek General Hospital Karachi during February 2018 to March 2020.

Materials and Methods: One hundred and eighty females with fibroadenoma as in breasts were administered evening primrose oil daily for 6 months. Pre therapy and post therapy size of the fibroadenoma was compared via ultrasound. The finding of ultrasound and lab investigation and demographic record was entered in design Performa. Written informed consent was taken before history and examination. The permission of Ethical Committee was taken before start of study and get publishing in Medical Journal. The data was analyzed for results by SPSS version 27.

Results: A total of 180 patients were able to complete the trial. There was no decrease in the size of fibroadenoma after therapy.

Conclusion: Evening primrose oil has no established role in management of breast fibroadenoma.

Key Words: Evening primrose oil, Fibroadenoma, Breast neoplasms.

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INTRODUCTION

Evening primrose oil is herbal medication extracted from seeds of a medicinal plant *Oenothera biennis*¹. Evening primrose oil contains linoleic acid, γ -linoleic acid, stearic acid, oleic acid, palmitic acid, and steroids campesterol and β -sitosterol. The basic indications of evening primrose oil described in literature are mastalgia^{2,3} and atopic dermatitis⁴. Evening primrose oil is rich in essential fatty acids which decreases the effect of estrogen on breast tissue and therefore help alleviating the mastalgia associated with menstrual cycle⁵.

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Fibroadenoma is a fairly common disorder of the breast with a reported incidence of 25% in asymptomatic women⁶. A local study showed that 45% of women presenting to clinic with history of breast lump had fibroadenoma⁷. Being a benign pathology most fibroadenomas are left alone without treatment, surgical resection is the most common intervention carried out if lump become enlarged, suspicious or if patient desires⁸. Other treatment modalities include cryoablation⁹, and high intensity focused ultrasound¹⁰. Fibroadenomas are found to have estrogen receptors and may lead to periodic growth of these swellings¹¹. Evening primrose oil may have a beneficial role in this context on fibroadenoma and hence preventing its further growth or even reduction in size. Our study evaluates the same hypothesis after administration of oral evening primrose oil for 6 months in female patients with fibroadenomas.

MATERIALS AND METHODS

This research was conducted under full accordance with the declaration of Helsinki. All the patients were kept anonymous, and data utilized only after obtaining informed consent.

This was a Quasi experimental study conducted at Creek General Hospital Karachi between February 2018 to March 2020. Approval from ethical review board was taken, and patients were enrolled in the trial only after obtaining informed consent. All females

presenting with breast fibroadenoma of size 5 cm or less (confirmed on ultrasound) were for non-surgical management were included in the study.

Inclusion criteria

All females between the age of 16 and 45 years presenting with breast fibroadenoma of size 5 cm or less (confirmed on ultrasound) who were selected for non-surgical management were included in the study.

Exclusion criteria

- Age less than 16 years or more than 45 years
- Multiple swellings in breasts or bilateral swellings
- Patients having menstrual irregularities
- Pregnancy and lactation
- Post-menopausal females with fibroadenoma
- Any comorbidities such as diabetes or hypertension
- Patients on oral contraceptives

All patients underwent ultrasound examination of breasts before commencing evening primrose oil therapy and size of the fibroadenoma was recorded. Patients were then prescribed evening primrose oil 4gm orally daily in divided dose for the period of 6 months. After the completion of therapy, a repeat ultrasound was carried out to assess the response of evening primrose oil. Paired t test was used to compare the significance of difference between the size reduction. The data was analyzed for results by SPSS version 27.

RESULTS

A total of 218 patients enrolled in the trial initially, however only 180 patients were available that were eligible for analysis. Out of the 38 dropped patients, 16 (42.10%) opted out for surgical excision, 8 (21.05%) patients had discontinued therapy on their own, 4(10.52%) patients conceived pregnancy and the remaining 10 (26.31%) patients were lost to follow up. The average size as noted on ultrasound prior to administering evening primrose oil was 2.76 cm (see figure – I). All of the patients had noticed the swelling as an incidental finding in duration of 8 months or less. Most of these patients had no pain associated with the swelling. Thirty percent (30%) of the ladies reported that they have taken self-medication (mostly multivitamins) in the past (see Table – I).

Table No.1: Patient data and comparison of size of the swelling

Patient Characteristic	Value (N = 180)	
Age	26.33±7.9 years	
Weight	69.0±8.70 kg	
BMI	23.6 ± 3.2 kg/m ²	
Duration of swelling	11.12±7.09 weeks	
Pre-therapy size	2.77±0.86 cm	P = 0.531*
Post-therapy size	2.71±0.74 cm	

* = Paired t test

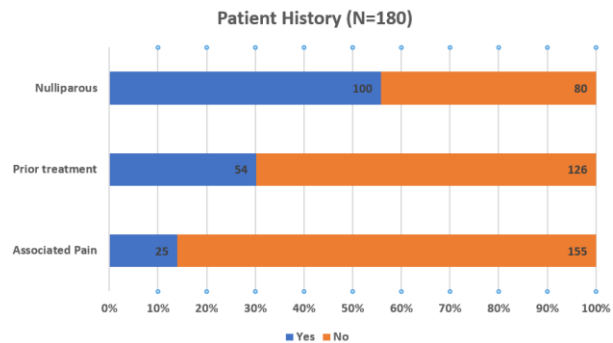


Figure No.1: Some history queries of the patients included in the study

No decrease in size of swelling was noted at the end of evening primrose oil therapy (P=0.531), in fact there were 21(11.66%) cases where there was increase in size of the swelling and 3(1.66%) case where a new swelling was noted in the same breast.

DISCUSSION

Fibroadenoma is the most common diagnosis in females presenting to surgical clinics with palpable breast masses¹². Although significant number of these females experience uncertainty and anxiety prior to the definitive diagnosis because of dread of having malignancy¹³, most after diagnosis of benign disease opt for conservative management as they are also afraid of cosmetic disfigurement and scar formation¹⁴. Although two thirds of fibroadenomas tend to resolve within five years without any sequelae¹⁵, medical treatment have been tried to manage these swellings. Danazol has been used in treatment of fibroadenoma but with disappointing results¹⁶.

Evening primrose oil has been used in treatment of various disorders such as mastalgia, attention deficit hyperactivity disorder, osteoporosis, rheumatoid arthritis, hypertension, diabetic neuropathy and weight loss¹⁷. Via animal trials evening primrose oil has also been found to be effective as an anticoagulant and anti-platelet agent^{18,19}. Evening primrose oil although found to reduce the effect of estrogen on breast tissue¹¹, in our study it showed no value in significant reduction in size or resolution of fibroadenoma. The reason why evening primrose oil was not able to reduce estrogen regulated growth of fibroadenoma is unclear and needs to be confirmed via conducting more scientific trials.

Our study was initially targeted for a study group that would be more than 500 patients but due to large number of drop outs and no ambiguity in the obtained results from study, we concluded our study early. Similar study has been done in international literature by Kollias J. et al²⁰. Their study had a prospective comparative design which is better than ours but their study inclusion and exclusion criteria were not well defined. No exclusion of patients on oral

contraceptives, any other hormonal therapy or any other comorbidities is mentioned. This may have affected the outcome of their study however their results also showed no benefit of evening primrose oil use for fibroadenoma.

CONCLUSION

Evening primrose oil although used frequently in cyclical mastalgia patients with good results, it has no role in medical management of breast fibroadenoma patients.

Author's Contribution:

Concept & Design of Study: Shamaila Ayub
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 Final Approval of version: Shamaila Ayub

Conflict of Interest: The study has no conflict of interest to declare by any author.

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