

EFFECTIVENESS OF VIT E VS EVENING PRIMROSE OIL IN TREATMENT OF PATIENTS WITH SYMPTOMATIC FIBROCYSTIC BREAST DISEASE-A COMPARATIVE STUDY



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KEYWORDS

INTRODUCTION

Fibrocystic breast disease (FBD) is the most frequent benign breast disease, which is diagnosed in 50% of the clinically and 90% of the histopathologically examined women.^{1,2}

Its highest incidence is between 20 and 50 years of age, when a woman is most exposed to stress throughout a her reproductive life and, and cyclical changes throughout the menstrual cycle.³ Fibrocystic breast disease affect about half of all women and typically present as any combination(s) of breast nodularity, swelling, and pain.

The changes in the breast physiologically/pathologically is put together by the Cardiff Breast Clinic as Aberration of Normal Development And Involution of Breast Tissue (ANDI). The pathogenesis of ANDI ranges from disturbances in the breast physiology extending from a perturbation of normality to well-defined disease processes. The symptoms of ANDI are varying as the term encompasses a wide range of benign conditions, but often include an area of fullness, lump and/or mastalgia.⁴

It is important to diagnose and treat fibrocystic breast disease timely since majority of it is benign. Available treatment includes reassurance, dietary changes, analgesics in symptomatic patients at initial stage and in moderate to severe cases by evening primrose oil, vitamin E, danazol, tamoxifen and progesterone.

Due to the high prevalence of fibrocystic breast disease and the adverse effects on quality of life, many drugs are being clinically tried to give symptomatic relief. Many studies are being done to compare the efficacy of different drugs in symptomatic relief of fibrocystic breast disease.

One of the commonest modalities of treatment is Vitamin E and Evening Primrose Oil. Evening Primrose oil contains variety of amino acids as lysine, tyrosine and Omega 6 fatty acids which produce as anti-inflammatory effects. Vitamin E is an antioxidant and acts by lowering reactive oxidative stress indicators and shields from harmful free radicals. As there is limited available literature comparing the efficacy of the two drugs in reducing mastalgia and nodularity, this study was done to compare their effect in symptomatic fibrocystic breast disease.

MATERIALS & METHODS

Study included a total of 64 patients in the study after taking ethics committee approval and proper consents. We included premenopausal women in the age group of 15-45 years, who were willing to participate in the study and with chief complaints of mastalgia or breast lump suggestive of fibrocystic breast disease. All patients with malignant diseases of breast or breast diseases other than fibrocystic disease such as fibroadenoma, infective breast disease, galactocele, previous breast malignancy or breast surgeries were excluded

There were two groups of patients, who were given Vitamin E (group A) and Evening Primrose Oil (group B) randomly (chit method).

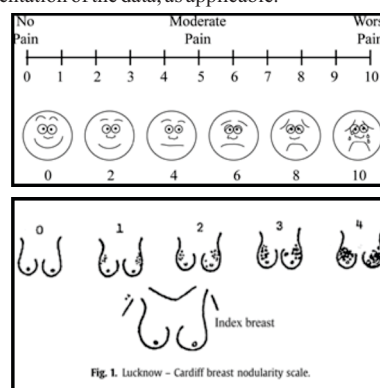
All patients in Vitamin E group were given orally 400 milligrams every day for 3 months, and those in Evening Primrose Oil group were given 1000 milligrams daily for 3 months orally. Clinical reassessment was done to evaluate the effect for both Vitamin E and Evening Primrose Oil after following up every week for first month and every 2 weeks from second month for total of 3 months.

Pain charting was recorded in the scoring chart VAS. Nodularity was

assessed by palpation and sonography, followed by grading according to Lucknow- Cardiff Scoring. We did a base USG, Nodularity Charting and Pain charting on first day before starting the treatment as a documentation.

Statistical Analysis

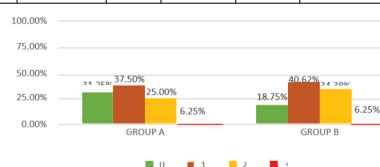
The data was analyzed using statistical software (IBM SPSS, IBM Corporation, Armonk, NY, USA). Descriptive statistics: The Numerical/Continuous data were expressed as Mean $\pm$ Standard Deviation and the Categorical data were expressed as Percentages. Analytical statistics: The Numerical/ Continuous data were analysed by the 'Paired t test' and 'Unpaired t test', as required. The Categorical data were analysed by the Chi square test (Fischer's exact test was used when more than 20% of the cells had value less than 5). P value of less than 0.05 was considered as "statistically significant" and indicated by "*" in the Tables. Bar charts, pie diagrams and line diagrams were used for the presentation of the data, as applicable.



RESULT

Table 1: Comparison Of The Grading Of The Nodularity During The Study Period In The Two Groups

TIME	NODU-LARITY	GROUP A		GROUP B		P VALUE
		N	%	N	%	
BASELINE	0	10	31.25	6	18.75	0.535
	1	12	37.50	13	40.62	
	2	6	18.75	10	31.25	
	3	4	12.50	3	9.38	
FIRST MONTH	0	10	31.25	6	18.75	0.679
	1	12	37.50	13	40.62	
	2	8	25.00	11	34.38	
	3	2	6.25	2	6.25	
SECOND MONTH	0	12	37.50	7	21.88	0.392
	1	12	37.50	15	46.87	
	2	8	25.00	10	31.25	
	3	2	6.25	2	6.25	
THIRD MONTH	0	14	43.75	8	25.00	0.013*
	1	18	56.25	17	53.13	
	2	0	0.00	7	21.88	
	3	0	0.00	0	0.00	



Graph 1: Comparison Of The Grading Of The Nodularity During The Study Period In The Two Groups

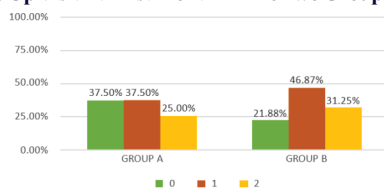
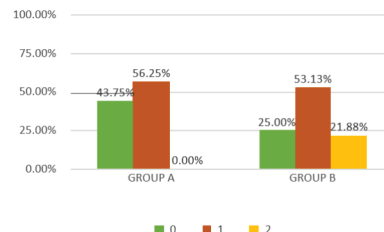
The Follow Up Visit At First Month In The Two Groups**Graph 2: Comparison Of The Grading Of The Nodularity During The Follow Up Visit At Second Month In The Two Groups****Graph 3: Comparison Of The Grading Of The Nodularity During The Follow Up Visit At Third Month In The Two Groups**

Table 1 and Graphs 1 to 3 show the comparison of nodularity in the two groups. The nodularity was similar in the two groups except at the end of the follow up period where the grades were consistently better in Group A than in Group B.

Table 2: Comparison Of The Presence Of Nodularity In The Post-treatment USG In The Two Groups

NODULARITY	GROUP A		GROUP B	
	N	%	N	%
PRESENT	18	56.25%	24	75.00%
ABSENT	14	43.75%	8	25.00%
TOTAL	32	100%	32	100%
P VALUE	0.114			
SIGNIFICANCE	Not significant			

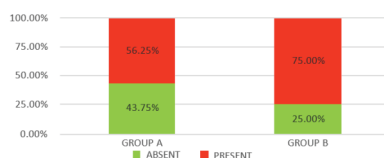
**Graph 4: Comparison Of The Presence Of Nodularity In The Post-treatment USG In The Two Groups**

Table 2 and Graph 4 show the distribution of nodularity in the post-treatment USG. It was similar in the two groups; P value: 0.114.

Table 3: Comparison Of The Pain Scores During The Study Period In The Two Groups

TIME	GROUP A		GROUP B		P VALUE
	Mean	SD	Mean	SD	
BASELINE	4.28	1.75	4.19	1.49	0.818
FIRST MONTH	3.50	1.55	3.03	1.06	0.163
SECOND MONTH	2.72	1.28	2.69	1.03	0.914
THIRD MONTH	1.81	1.06	2.13	0.83	0.195

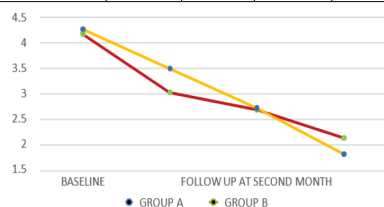
**Graph 5: Trends In The Mean Pain Scores During The Study Period In The Two Groups**

Table 3 and Graph 5 show the comparison of pain scores in the two groups.

The pain scores were similar in the two groups throughout the follow up period.

DISCUSSION

Fibrocystic breast disease is common benign breast disease with high incidence during the reproductive age. The incidence of benign breast disease within a population is 13.5% to 42%.³

In the present study, it was observed that in most of the cases of fibrocystic breast disease there was consistent reduction in the nodularity grades in comparison to the baseline upon comparing nodularity grading in Group A receiving Vitamin E during the follow up period of three months. At the beginning of the first month 69% of the patients had nodularity in Group A which got reduced to 56% at the end of three months out of which all Grade 3 and Grade 2 improved to Grade 1.

All patients who were receiving Evening Primrose Oil (Group B) 81% presented with nodularity at the start of the study. At the end of the follow up period of three months 11% of the cases improved to Grade 1 nodularity and in total 7% of the cases improved to Grade 0. However, there were still 7 cases with Grade 2 nodularity after the end of the study.

When the two groups were compared, it was observed that the baseline nodularity was similar in the two groups; P value: 0.535. The changes in nodularity were similar in the two groups at the first and second month of follow up; P value: more than 0.05. However, the grades of nodularity at the end of the follow up were significantly less in Group A as compared to Group B; P value: 0.013.

Vitamin E was found to be effective in reducing nodularity in the study by Godazandeh G. et al¹ in which study was conducted in 100 patients with mastalgia and nodularity receiving Flaxseed oil and Vitamin E in 2021.

In this other study-A Randomized Controlled Multicenter Trial of an Investigational Liquid Nutritional Formula in Women with Cyclic Breast Pain Associated with Fibrocystic Breast Changes done by Robert E. Mansel, Tapas Das, Geraldine E. Baggs, Michael J. Noss, William P. Jennings, Jay Cohen, David Portman, Mario Cohen, and Anne Coble Voss in 2018 stated that women who took medications with a formula containing GLA (evening primrose oil) reduced nodularity as compared to women who took over the counter pain medications such as NSAIDs.¹⁵

Thus, it was found that there is a significant reduction in the grades of nodularity in Group A receiving Vitamin E as compared to Group B receiving Evening Primrose Oil.

In the present study, it was observed that 29 patients had mastalgia as a symptom in Group A receiving Vitamin E and 86% of them showed drastic improvement symptomatically. There was a consistent reduction in the scores during the course of treatment as compared to baseline; observed mean pain scoring showed significant decrease from 4.28 + 1.75 to 1.81 + 1.06, P value: less than 0.05.

The cases receiving Evening Primrose Oil (Group B), 90% of them showed symptomatic improvement in terms of mastalgia. The mean pain score in Group B also showed a significant decrease from 4.19 + 1.49 to 2.13 + 0.83.

When the pain scores were compared in the two groups, it was observed that the scores were similar in the two groups at baseline and throughout the follow up period. P value: more than 0.05.

Vitamin E has been found to be effective in the treatment of breast pain in studies by Godazandeh G, Ala S, Motlaq TM, Sahebnaasagh A, Bazi A -The comparison of the effect of flaxseed oil and vitamin E on mastalgia and nodularity of breast fibrocystic: a randomized double-blind clinical trial⁸ in 2021 and in different study by Parsay S, Olfati F, Nahidi S- Therapeutic effects of vitamin E on cyclical mastalgia which shows Vitamin E to be as effective in reducing mastalgia in 2009.⁶

Similarly, EPO has also been found to be effective in other studies by Qureshi S, Sultan N in 2005 - Topical nonsteroidal anti-inflammatory drugs versus oil of evening primrose in the treatment of mastalgia and Alvandipour M, Tayebi P, Avaie R, Khodabakhshi H in 2011- Comparison between Effect of Evening Primrose Oil and Vitamin E in Treatment of Cyclic Mastalgia.⁹⁻¹³

Thus, from the present study we found that pain scores were

significantly reduced at the end of treatment after 3 months in both the group A and group B.

CONCLUSION

In this study on the effectiveness of Vitamin E and Evening Primrose Oil, where 64 patients with symptomatic fibrocystic breast disease were compared in terms of pain and nodularity. We concluded that Vitamin E was found to be more effective in decreasing nodularity compared to Evening Primrose Oil, while both Vitamin E and Evening Primrose Oil are equally effective in improving mastalgia. Therefore, we can conclude that Vitamin E can be considered as a better medication than Evening Primrose Oil in the treatment of symptomatic fibrocystic breast disease. Furthermore a combination of both Vitamin E and Evening Primrose Oil can be more beneficial.

Limitations

The present study is limited by small sample size and done at a single centre. Therefore, a study with larger sample size with involvement of multiple centres is required to reach a better conclusion.

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REFERENCES

1. Rinaldi P, Ierardi C, Costantini M, Magno S, Giuliani M, Belli P, et al. J Ultrasound Med. 2010;29(11):1617–1626.
2. Kelsey JL, Gammon MD. Epidemiology of breast cancer. Epidemiol Rev 1990; 12:228–240.
3. Caleffi M, Filho DD, Borghetti K et al. Cryoablation of benign breast tumors: evolution of technique and technology. Breast 2004; 13:397–407.
4. Cole P, Mark Elwood J, Kaplan SD. Incidence rates and risk factors of benign breast neoplasms. Am J Epidemiol 1978;108:112–120.
5. Bayles B, Usatine R. Evening primrose oil. Am Fam Physician 2009;80:1405-8.
6. Parsay S, Olfati F, Nahidi S. Therapeutic effects of vitamin E on cyclic mastalgia. Breast J 2009;15:510-4.
7. Jaafarnejad F, Adibmoghaddam E, Emami SA, Saki A. Compare the effect of flaxseed, evening primrose oil and Vitamin E on duration of periodic breast pain. J Educ Health Promot. 2017;6:85.
8. Godazandeh G, Ala S, Motlaq TM, Sahebnaasagh A, Bazi A. The comparison of the effect of flaxseed oil and vitamin E on mastalgia and nodularity of breast fibrocystic: a randomized double-blind clinical trial. J Pharm Health Care Sci. 2021 Jan 6;7(1):4.
9. Pashby NL, Mansel RE, Hughes LE, et al. A clinical trial of evening primrose oil in mastalgia. Br J Surg. 1981;68:801.
10. Cheung KL. management of cyclic mastalgia in oriental women : Pioneer experience of using gamolenic acid (E Famast) in asia . Aust NZJ Sug. 1999;69(7):492-4.
11. Qureshi S, Sultan N. Topical nonsteroidal anti-inflammatory drugs versus oil of evening primrose in the treatment of mastalgia. Surgeon. 2005;3:7–10.
12. Alvandipour M, Tayebi P, Avaie R, Khodabakhshi H. Comparison between Effect of Evening Primrose Oil and Vitamin E in Treatment of Cyclic Mastalgia. Journal of Babol University of Medical Science. 2011;13(2):7-11.
13. Ahmad Adni L, Norhayati MN, Mohd Rosli RR, Muhammad J. A Systematic Review and Meta-Analysis of the Efficacy of Evening Primrose Oil for Mastalgia Treatment. Int J Environ Res Public Health. 2021 Jun 10;18(12):6295.