

Comparative Study Between Evening Primrose Oil And Ormeloxifene in mastalgia

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Abstract :

INTRODUCTION : Mastalgia accounts for about 50 % of the benign breast . A number of drugs have been introduced in the treatment of mastalgia ,still debate continues about the drug of choice.

MATERIAL & MTHODS : This was a prospective study done on 100 patients , who were either given EPO or ormeloxifene for 6 months .Patients were followed up upto 1 year .

OBSERVATION & RESULT : There was a significant difference in the pain relief obtained in group of patients taking ormeloxifene .

CONCLUSION : Ormeloxifene can be the drug of choice in mastalgia of benign origin .

Keywords : Mastalgia , ormeloxifene , evening primrose oil ,

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I. Introduction

Mastalgia (breast pain) was described in the medical literature as early as 1829 and is a common complaint amongst women [1]. Pain accounts for upto 50% of patients with benign breast disease. There are two distinct group of patients with these symptoms (a) Cyclical mastalgia - which bears a definite relationship to the menstrual cycle (b) Non cyclical mastalgia .-which has no correlation with menstrual cycle. Many theories have been implicated as the cause of mastalgia like estrogen excess ,progesterone deficiency ,changes in estrogen progesterone ratio, difference in receptor sensitivity, disparate secretion of FSH and LH ,low androgen levels and raised prolactin levels [2] . A number of drugs have been introduced in the treatment of mastalgia .They are-----OCPs ,diuretics ,vitamin A, vitamin B6, vitamin E ,bromocriptine, tamoxifene, EPO, medroxyprogesterone acetate ,iodine, NSAIDS ,gestrinone ,thyroid hormones [3] . Still considerable debate occurs about the drug of choice for management of mastalgia . Cap EPO is an extract from a plant which is found in many parts of North America. EPO is omega fatty acid resin containing both linolenic acid {LA} and gamma linolenic acid {GLA} .EPO contains 74% LA, 11% oleic acid, 9% GLA, 6% palmitic acid ,2% stearic acid .It has been seen that women with breast pain have usually low concentrations of GLA and metabolites .Cap EPO is a dietary supplement and has been investigated in depth for its effectiveness for conditions that are associated with deficiency in essential fatty acids .EPO has a good safety profile with mild side effects and rare serious adverse events .EPO should not be taken during pregnancy ,prior to surgery ,in patients at risk of seizures or taking phenothiazines and related medications, anti platelets ,thrombolytics, low molecular weight heparin or anticoagulants[4] .Ormeloxifene (or novex / centchroman) is one of the selective estrogen receptor modulator or SERMS-- a class of drugs which acts on the estrogen receptor (weak ER agonist ,a strong ER antagonist).In some parts of the body, its action is estrogenic (eg bone) ,in other parts of the body, its action is antiestrogenic (eg uterus ,breast) .Ormeloxifene has been tested and licensed as a form of birth control pill as well as a treatment for DUB .Adverse effect is delayed menses .[5] . This study was done to compare the effect of Ormeloxifene and EPO in mastalgia.

II. Material & Methods

This was a prospective randomized control trial study done in obs & gynae OPD of RIMS ,Ranchi, Jharkhand ,India from February 2017 to July 2018. Proper history was taken from patients coming to OPD with complains of mastalgia. Clinical examination and high resolution sonography was done to rule out any pathological cause. All patients with breast pain with mastalgia in the age group of 15 to 50 were included in the study. Patients who were pregnant / lactating, had lump in the breast ,had history of breast carcinoma ,had family history of breast carcinoma ,had breast abscess ,had any history of breast injury or any other non mammary cause of chest pain were excluded from the study. Informed consent was taken from patients ,was witnessed and formally recorded .Patients were randomly divided into two groups of 50 each. Group A: EPO

tablet containing evening primrose oil (1000 mg) was given everyday continuously for 6 months. Group B : Ormeloxifene was given in doses of 30 mg tablet every alternate day for 6 months . Follow up was done at the end of 3rd month , 6th month and 1 year to assess relief in breast pain ,to assess the side effects of each drug and to assess the recurrence of symptoms after the completion of treatment. The result was analyzed using chi square test [χ^2] .

III. Observation & Result

Both the groups were followed .At the end of 3rd month ,40 (80%) patients of ormeloxifene group had complete relief whereas only 05 (10%) of EPO group had complete relief [$\chi^2 = 49.8$, $p < 0.001$] .

Table 1 : comparison of degree of relief between EPO and ormeloxifene group at the end of 3rd month

Degree of relief	EPO	Ormeloxifene
(805	45 (90%)	10 (20 %)
Complete relief	05 (10%)	40(80%)

At the end of 3rd month when we enquired about any problem associated with the EPO group , 13 (26%) of the patients complained about gastro – intestinal symptoms like belching ,nausea & vomiting and gastric intolerance whereas 12 (24%) patients complained about delayed menses .

Table 2 : comparison of side effects between EPO and ormeloxifene group at the end of 3rd month

Side effects	EPO	Ormeloxifene
Belching ,nausea & vomiting ,gastric upset	13 (26%)	00
Oligomenorrhoea	00	12 (24%)

At the completion of treatment , 48 (96%) patients of ormeloxifene group had complete relief whereas 10 (20%) of EPO had complete relief [$\chi^2 = 59.26$, $p < 0.001$]

Table 3 : comparison of degree of relief between EPO and ormeloxifene group at the end of 6th month

Degree of relief	EPO	Ormeloxifene
Not complete relief	40(80 %)	02(04%)
Complete relief	10(20%)	48(96%)

At the end of 6th month , 21(42%) patients had gastro – intestinal symptoms whereas 24 (48%) had oligomenorrhoea .

Table 4 : comparison of side effects between EPO and ormeloxifene group at the end of 6th month

Side effects	EPO	Ormeloxifene
Belching ,Nausea & vomiting ,gastric upset	21 (42%)	00 (0 %)
Oligomenorrhoea	00 (0%)	24 (48 %)

Patients were followed upto 1 year to observe if there was recurrence of pain , 22 (44%) patients of EPO group had developed the symptoms again whereas only 2 (4%) in ormeloxifene group .

Table 5 : comparison of pain recurrence between EPO and ormeloxifene at the end of 1 year

	EPO	Ormeloxifene
Pain recurrence	22 (44%)	2(4%)

IV. Discussion

Dhar et al studied the role of centchroman in regression of mastalgia and fibroadenoma .There was a good response in the mastalgia group with a decrease in the Visual Analogue Scale (VAS) scoring from 10 to 3 in 90% of the patients in the first week .Almost all the patients were painless at the end of one month . [7] Khanna et al did a comparative evaluation of centchroman 30 mg ; Danazol 50 mg and EPO 1000 mg bd .Treatment was given for 3 months and patients were followed up for 6 months. All three subgroups showed at least 50% reduction in pain after 3 months of treatment but at 6 months follow up ,VAS was >4 in 13.33% patients in centchroman group ,64.7% patients in danazol group .and 70.5 % patients in EPO group [8] Mohakul et al studied centchroman in benign mastalgia of diverse origin . Excellant response to the treatment was noticed in most of the patients . 57.14 % were pain free at the end of one month ,82.14 % by the end of second month ,92.8 % had no pain by the end of third month ,4.8 % persisted with mild pain .In 2. 4 % no change in the severity was noticed .The adverse effects noted were 8 .33 % of either oligomenorrhoea or

hypomenorrhoea, 2.38 % of menorrhagia and 2.38 % of hot flushes .[9] Dhar et al did a comparative study of centchroman vs danazol vs EPO in the management of mastalgia and fibroadenoma .Total 117 patients participated in the study (mastalgia -68 ,fibroadenoma 54 and 5 patients had both) .In mastalgia group 28 ,18 and 22 patients were treated with centchroman ,danazol and EPO respectively . Centchroman was found to be the most effective drug with the post intervention pain scores <2 in 71 % patients (50 % with danazol ,0 % with EPO) . In fibroadenoma group, response rate was highest in centchroman arm (29 %) in comparison to danazol (17 %) and EPO (0 %) respectively . Side effects are maximum with danazol and minimum with centchroman [10] . Bansal V et al studied the efficacy of ormeloxifene in the treatment of mastalgia and fibrocystic breast disease .The mean pain level continuously decreased over 5 visits (5 .8 to0.86) and there was significant improvement in the nodularity grades . [11] Kumar Sandeep et al in their double blind ,placebo controlled trial of ormeloxifene in breast pain and nodularity showed a systematic downward trend of the mean pain level over 5 visits ($F=105.23$, $P < 0.0001$ vs $F=18.66$, $P < 0.0001$) . Oligomenorrhoea alone was reported by 12 patients . They concluded that ormeloxifene has significant efficacy in treating breast pain and nodularity . J Rathi et al in a single arm ,open label prospective study on ormeloxifene in mastalgia and breast nodularity observed that there was a remarkable decrease in the median pain duration over time . The drug was found more effective and with a quicker response in cyclic pattern of mastalgia . Complete response was observed in 66% of cyclic mastalgia and 40% of noncyclic mastalgia at 1 week of therapy . The response was improved over time in both groups and at completion (24 weeks) of the study .

V. Conclusion

Breast pain of benign origin is a common problem nowadays ,still it does not have a drug of choice . Ormeloxifene may be the drug of choice in mastalgia , both for cyclical and non cyclical type .

References

- [1]. Bansal V : Efficacy of Sevista (ormeloxifene) in the treatment of mastalgia and fibrocystic disease. *Int J Reprod,Contracept Obstet Gynaecol*.2015 Aug;4(4);1057-1060 .
- [2]. S Das : *A Concise Textbook of Surgery* ;5th edition (page 700)33
- [3]. N Thakur : Use of EPO in treatment of mastalgia . *The Internet Journal of Surgery VOL 24;Mastalgia* .
- [4]. Wikipedia
- [5]. Dhar A, Srivastava A : *World J Surg* 2007 Jun;31 (6): 1178-84
- [6]. Seema Khanna ,Dayanand Gupta :Comparative evaluation of the role of centchroman in benign breast disease *Int J of Biomed Res* 40 :
- [7]. Subrat kr Mohakul , Sujata Guttala , Purnima Tiru Role of ormeloxifene (centchroman) in Benign Mastalgia of Diverse Origin ; *Scient Open Access Journal : Women's Health & Gynaecology*
- [8]. Debasis Dhar , Parthasarathi Ghosh ; A Comparative study of centchroman vs danazol vs EPO in the management of mastalgia and fibroadenoma ; *International Journal of Scientific Research vol -6 issue - 2,feb 2017*
- [9]. Sandeep Kumar , Ruchi Rai : A randomized double blind ,placebo controlled trial of ormeloxifene in breast pain and nodularity ;*The National Medical Journal of India Vol 26 ,No 2,2013* .
- [10]. Jalaj Rathi : Centchroman ; a first line treatment for mastalgia :Results of an open label single arm trial : *The Breast Journal Vol 22 issue 4 july/aug 2016 pages 407 – 412+*

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