Original Research Paper

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ORMELOXIFENE USE IN FIBROCYSTIC DISEASE OF BREAST COMPARED TO EVENING PRIMROSE OIL

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INTRODUCTION

Fibrocystic disease of breast commonly called fibrocystic change or fibrocystic breast is a benign condition diagnosed in millions of women world wide.Fibrocystic breast changes occur most often in women in their 20s to 50s. Rarely do postmenopausal women experience fibrocystic breast changes, unless they're on hormone therapy.Symptoms of fibrocystic disease are cyclical breast pain, tenderness, lumps, nipple discharge in few. The condition is likely due to hormonal changes during menstrual cycle that affect breast tissue. Many drugs have been introduced for its treatment like OCPs, Vit A,Vit B6,Vit E,bromocriptine, tamoxifene, EPO, Medroxyprogesterone acetate, NSAIDS.Cap EPO is an extract from a plant which is found in many parts of North America.Evening primrose oil (EPO) is omega fatty acid resin containing both linolenic acid and gamma linolenic acid(GLA) . It has been seen that women with breast pain have low concentration of GLA and metabolites. Cap EPO dietry supplement is effective in condition with deficiency of essential fatty acids. EPO has good safety profile and mild side effects. Ormeloxifene is one of the selective estrogen receptor modulator or SERMs acts on estrogen receptor. It's action is estrogenic in some parts eg. Bone in other parts it's action is anti estrogenic eg. Uterus and 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 .This study was done to compare role of ormeloxifene and EPO in fibrocystic disease of breast.

AIM OF STUDY

● To compare the role of ormeloxifene and evening primrose oil in fibrocystic disease of breast

MATERIALS AND METHODS

Type of study: A normal randomised prospective observational study.

Place of study: Department of obstetrics and gynaecology, DMCH, Laheriasarai, Bihar.

Sample size: A total of 100 cases will be studied of which patients will be randomly divided into 2 groups of 50 each. Group A: evening primrose oil (1000mg) will be given continuously for 3 months. Group B:ormeloxifene will be given in doses of (30mg) tablet every alternate day for 3 month.

Study population: From Darbhanga, samastipur, madhubani, sitamadhi and nearby area.

Inclusion criteria:

1.All female patients aged 16-35 year with a history of benign breast disease.

2.patients with history of breast pain with or without tender nodularity.

3.cases of fibroadenoma (<4cm) after triple assessment (clinical exam, usg, fnac).

Exclusion criteria:

Patients who were pregnant / lactating, hard 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.

Any contraindication to ormeloxifene and evening primrose oil as hypersensitivity

METHODS

A complete general, gynaecological examination was done. Blood testing was done for hemoglobin, LFT, KFT, done. Triple assessment was done in cases of fibroadenoma. Informed consent taken from patients. Group A patients are advised to take evening primrose oil (1000) mg everyday continuously for 3 months. Group B patients: ormeloxifene was given in doses of 30 mg tablet every alternate day for 3 month. Clinical reassessment done at the end of 1month, 3month, 6month and 1year follow up. Radiologic breast re evaluation done at the end of 1mnth, 3mnth, 6mnth.

Parameters to be studied:

To assess relief in breast pain.
To assess side effects of each drug.
To assess recurrence of symptoms after completion of treatment.

Statistical Analysis:

Data will be calculating mean, standard deviation, standard error, and percentage distribution of variables.

Student's t test, Chi square test and p value estimation will be used.

RESULTS:

In our study, after 12 weeks of treatment with Ormeloxifene 80% were relieved of mastalgia (mean pain score ≤3).

• After 24 weeks 95% patient were relieved of (2 patients were shifted to danazol at end of 3 months of treatment).

• After one month of treatment reduction in pain which was recorded on visual analogue scale was similar in both the groups. But patients in group 1 (ormeloxifene) recorded a greater reduction in pain on VAS pain scale at the end of second and third month when compared to patients in group 2 (evening primrose oil).

• Ormeloxifene is more effective than evening primrose oil in long term in the treatment of mastalgia.

• Patients in Ormeloxifene group experienced early alleviation of mastalgia as compared to patients in evening primrose oil group.

• In our study out of the 50 patients in Ormeloxifene group, 12 patients had oligomenorrhoea at the end of 3 month and 24 patients had oligomenorrhoea at the end of 6 month. No other side effects seen with this group.

• In our study mild side effect was seen with use of evening primrose oil. Out of 50 patients only 13 patients reported with side effects such as belching, nausea, vomiting, gastric upset.

CONCLUSION:

Ormeloxifene is significantly better than Evening Primrose Oil (EPO) in causing regression of breast lumps in fibroadenomas. Ormeloxifene is significantly better than EPO in causing relief from breast pain in benign breast disease. Ormeloxifene is significantly better than EPO in regression of tender nodularity in patients of fibrocystic disease of the breast. Both Ormeloxifene and EPO have excellent safety and side effect profile with no serious adverse effects reported in either of the treatment groups.

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