

Study of Various Drugs in Aberrations of Normal Development and Involution and Fibroadenosis

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Abstract :

Periodic mastalgia in female patients is a very significant cause for absence from work, and at times inability to carry out routine day to day work. Aberrations of Normal Development and Involution (ANDI) and specifically fibrocystic diseases correspond to a large percentage of such patients. Till date except for tamoxifen no specific drugs were used. As compared to those drugs, Tablet Saheli (ormeloxifene) is cheap, easily available with minimum side effects and convenient dosage of twice a week makes in the drug of choice of such patients, if efficacy is well proved. A prospective study of 80 patients with fibrocystic disease of breast and mastalgia was carried out from the period of July 2012 to October 2018 at Civil Hospital, Ahmedabad. All infective conditions, congenital anomalies and other benign breast conditions like fibroadenoma were excluded. The aim of our study was to study the usefulness of various drugs commonly used in mastalgia and fibroadenosis. Out of 80 patients, 40 were started on Tab. Saheli (ormeloxifene), 38 on evening primrose oil and 2 on danazol. Out of 40, 80% (32 patients) had complete response with Tab Saheli (ormeloxifene). Out of 38 patients, who were started on evening primrose oil, 50% (19 patients) had complete response and out of 2 patients started on danazol, 50% (1 patient) had complete response. The rest 28 (35%) patients were not relieved of their symptoms even after 6 months.

Keywords : Danazol, Fibroadenosis, Saheli

Introduction :

Periodic mastalgia in female patients is a very significant cause for absence from work, and at times inability to carry out routine day to day work. ANDI and specifically fibrocystic disease corresponds to a large percentage of such patients. Till date except for tamoxifen no specific drugs were used. As compared to those drugs, ormeloxifene is cheap, easily available with minimum side effects and convenient dosage of twice a week makes in the drug of choice of such patients, if efficacy is well proved.

Objectives :

To study the use of various drugs, specifically the role of Tab. Saheli (Ormeloxifene) in the management of ANDI and fibroadenosis of breast with a follow up at 0, 1 and 6 month intervals.

Methods:

A prospective study of 80 patients with fibrocystic disease of breast and mastalgia was carried out from the period of July 2012 to October 2018 at Civil Hospital Ahmedabad. Females in the age groups from 16 to 50 years were included in the study. Along with clinical correlation, mammography was carried out for females more than 35 years of age and Ultrasound of breast was carried out if any diagnostic dilemma was present.

Exclusion criteria :

Patients with a discrete lump, which was suspicious of cancer after clinical, imaging and cytological examination, were excluded from the study. Also patients taking alternative treatment, lactating women, those planning a pregnancy or taking other oral contraceptive pills were also excluded. Women suffering from polycystic ovarian disease, other hormonal abnormalities requiring additional investigations, and liver and kidney problems were also excluded from the study.

Tab Saheli (Ormeloxifene) was started at a dose of 30 mg twice a week for 1 month and patients were followed up at 1 month. Tab. Saheli (ormeloxifene) was stopped

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after 1 month for those patients in whom the symptoms were relieved which was assessed by decrease in pain as per visual Analogue Scale⁽¹⁾ (Figure 2) or decrease in nodularity as per Lucknow Cardiff Scale⁽²⁾ (Figure 1). Patients in whom the pain was not relieved, Tab. Saheli (ormeloxifene) 60mg twice a week was started and asked to continue till 6 months with a regular follow up every month. Results were assessed at the end of 6 months. The complaint of mastalgia was assessed as per Visual Analogue Scale. The complaint of nodularity was assessed by Lucknow Cardiff scale. This scale is a 5-point ordinal scale depicting increasing order of nodularity shown schematically in the upper outer quadrants of breast where Grade 0 indicates a smooth textured breast with extreme extent of normalcy and grade 4 the maximum nodularity. There were five figures that provide a cue for the examining physician to chart nodularity in the index breast. The examining physician makes a holistic interpretation of breast nodularity as a sum of areas or quadrants involved and the coarseness of nodularity. Breast nodularity was assessed longitudinally, by the same clinician on an ordinal scale of 0–4 in the breast clinic at each visit.

Figure 1: Lucknow-Cardiff breast nodularity scale

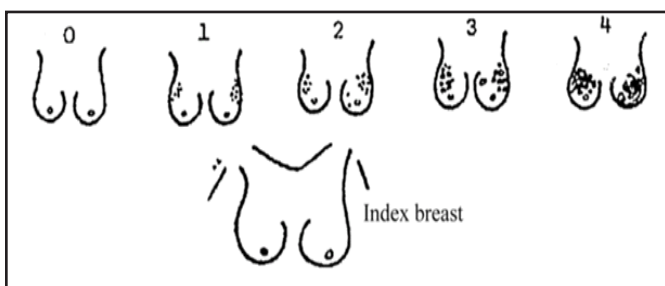


Figure 2 : Visual Analogue Scale

DAILY BREAST PAIN CHARTING

Daily Breast Pain Chart
Name _____ Age _____
नाम _____ उम्र _____

Record the amount of breast pain you experience each day by shading in each box as shown. Severe pain अत्यधिक दर्द
प्रतिदिन स्तन में होने वाले दर्द के अनुसार दिखाये गये तरीके में प्रत्येक खाने को रंगिए।

For example: If you get severe breast pain on the fifth day of the month then shade in completely the square under 5. Mild Pain मामूली दर्द
उदाहरण: यदि माह की पाँचवीं तारीख को आपको स्तनों में अत्यधिक दर्द होता है तो 5 के नीचे वाला खाना पूरा रंगें।

Please note the day your period starts each month with the letter 'P'. No Pain कोई दर्द नहीं
इस माह जिस तारीख को मासिक शुरु हो उस दिन के कोष्ठ में 'म' लिखें

माह	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

Note : Please bring this card with you on each visit.
नोट : कृपया हर बार यह कार्ड अपने साथ लायें।

Results and Discussion :

Table 1 : Management of mastalgia & type of response (Total 80):

Variable	Complete Response	Partial Response	No Response	Total
Evening primrose oil	19	17	2	38
Saheli (Ormeloxifene)	32	7	1	40
Danazol	1	1	0	2
Total (%)	52 (65%)	25 (31.25%)	3 (3.75%)	80 (100%)

Out of 80 patients, 38 pt. were given Cap. Evening primrose oil, 19 (50%) showed complete response, 17 had partial and 2 showed no response; 40 patients started on Tab. Saheli, 32 (80%) patients were relieved by Tab. Saheli (ormeloxifene) 30mg twice a week at the end of 1 month and 7 (17.5%) of them were relieved after 6 months with Tab. Saheli (ormeloxifene) 60mg twice a week. The rest 1 patient was not relieved of their symptoms even after 6 months. Out of 2 patients treated with Tablet Danazol 1 showed complete response and 1 showed partial response. Out of 80 patients with ANDI included in the study, maximum number of patients (26%) presented with bilateral nodularity. Maximum prevalence (24%) was found to be in females in the age group 31-40 years who presented with the complaint of nodularity.

The minimum prevalence was found to be the presence of nodularity in the age group 41-50 years (2%). Among the age group of 10-20 years and 21 to 30 years the patients presented chiefly with the complaint of mastalgia (10% and 12% respectively). Out of 80 patients with ANDI and fibroadenosis included in the study, 40 patients were given Tab. Saheli (ormeloxifene) and 39 patients benefitted from it. There was improvement in both the nodularity and mastalgia.

A study conducted by Srivastava and Dhar⁽³⁾ published in the World Journal of Surgery also concludes 90% regression in the mastalgia group at the end of 1 week and almost 100% resolution at the end of 1 month. A clinical trial conducted in All India Institute of medical sciences, New Delhi, India reported at the end of three

month of treatment 90% patients were pain-free with complete disappearance of nodularity.

A study from the IOSR (The International Organization of Scientific Research) journal in 2007 on the role of Tab. Saheli (Ormeloxifene) in treatment of mastalgia and fibrocystic disease by Dr. Anjana Gandhi⁽⁴⁾ quoted "At the end of third month of treatment, 83.7% had grades 1 and 2 while grades 3, 4 and 5 were seen only in 16.3% patients. After two months without treatment (at the end of sixth month), 92.6% patients had grades 1 and 2 and only 7.4% had grade 3, 4 and 5 nodularity. Mean pain assessment at successive visit for ormeloxifene revealed; mean pain score at beginning of treatment 5.82, at the end of first month 4.76, at the end of second month 2.08, at the end of third month 1.21 & at the end of sixth month 0.86."

Conclusion:

Mastalgia and Nodularity were common presentations in fibrocystic diseases of the breast. The most common age group presenting to us was between 31 to 40 years who presented with the complaint of nodularity. Mastalgia was common presenting complaint in the age group 10-20 years and 21-30 years. Out of the various drugs commonly used in fibroadenosis, Tab. Saheli (ormeloxifene) was found to be the most beneficial. out of 40 patients who were started on Tab Saheli (ormeloxifene), 80% patients were relieved at the end of 1 month and 17.5% of them were relieved after 6 months treatment, thus concluding Tab. Saheli (Ormeloxifene) to be a useful and safe drug in the management of mastalgia and fibrocystic disease.

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Further reading:

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6. Sabiston's textbook of surgery volume 1, 20th edition.