

## Spectrum of Presentation of Benign Breast Diseases and Role of Danazol in its Management in a Tertiary Care Hospital of South Odisha, India

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### ABSTRACT

**Objective:** To assess different spectrum of presentation of Benign breast diseases (BBD) and role of the drug Danazol in management.

**Materials and methods:** This was a prospective study. 92 patients of benign breast disease (BBD) were taken as study population. All the patients with complains of pain and lump in the breast with diagnosed case of benign breast disease in OPD or admitted in Department of General Surgery, M.K.C.G. Medical College & Hospital, Berhampur, were taken into consideration for the study period from July 2017 to June 2019.

**Results:** In this study it is found that, most common benign breast disease found to be fibroadenoma 52%, followed by fibroadenosis 40%, phylodestumour 5% and duct ectasia 3%. Incidence of benign breast disease was more in adolescent and young adult female around 70%. Danazol in a dose of 100mg twice daily orally and short course of 3 months could result in elimination of nodularity and pain in 62.5% in fibroadenosis, decrease symptoms of fibroadenosis in 30% cases and no response in 7.5%. Side effects of Danazol were also found but it was only 5% as menstrual irregularities and 2.5% had weight gain and rest 92.5% had no side effect.

**Conclusion:** Endocrine manipulation in benign breast disease by using Danazol in low dose and short period result in reduction of tumour size with minimal side effect significantly.

**Key words:** Benign breast disease, Danazol, Fibroadenosis

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### INTRODUCTION

Benign breast disease (BBD) is a major concern in young adult female due to lack of knowledge and fear of surgical procedure and its complication. Most cases are relieved without any treatment, only by reassurance and breast support with sports bra. But there are so many pharmacological agents used in the treatment of benign breast disease. Benign breast diseases are thought to be

due to cyclical hormonal response. So the drugs which induce hormonal manipulation are used. Danazol a derivative of synthetic steroid ethisterone in a low dose and short period was very effective in treating benign breast disease like fibroadenosis and breast pain.

Breast is the emotional symbol of women's pride in her sexuality and motherliness. To threaten the breast is to shake the very core of her femininity. The female breast is part of women's identity and femininity, particular through the role that the breast plays in experiences of puberty, motherhood, sex, health and ageing [1]. Benign condition account for 90% of the clinical presentations related to the breast. About 30% of all women suffer from breast disorders requiring treatment at some time in their life time. Benign disorders of the breast are usually seen in the reproductive period of life, thought to be largely hormone induced. There is a dramatic fall in the incidence after menopause due to

cessation of clinical ovarian stimulation. Benign breast disease is 4-5 times more common than breast cancer. The concept of Aberrations of Normal Development and Involution (ANDI) is gaining acceptance. Most benign breast diseases are relatively minor aberration of normal process of development, cyclical hormonal response, pregnancy and lactation related and involution that interact throughout a women's life [2]. As the recurrence and bilateral occurrence reported results in benign breast disease, surgical excision is being avoided unless histopathological evidence of potential malignancy exists [3]. Estrogen predominance and progesterone deficiency are the pathophysiologic hallmarks that result in hyper proliferation of connective tissue (fibrosis), followed by facultative epithelial proliferation. Therefore, the ideal treatment of benign breast disease should be directed towards suppression of ovarian oestrogen secretion with a low-estrogen oral contraceptive, or by the administration of a progestogen that modulates the mammary effects of estrogen [4]. Different hypotheses for mastalgia have led to use of different medical and non-medical therapies. The mastalgia may be caused by either increased oestrogen secretion from ovary, deficient progesterone production and increased prolactin secretion. Many pharmacological agents have been tried in the therapy of mastalgia. The drug therapy includes agents inducing hormonal manipulation such as Danazol, Bromocriptine, Tamoxifen, and LH-RH analogue like Goserelin. Some of the effective non-hormonal agents in mastalgia are Non-steroidal anti-inflammatory gels, reassurance and breast support with sports bra. There is considerable debate about drug of choice for management of mastalgia [5]. Danazol, which is a derivative of the synthetic steroid ethisterone, a modified testosterone, suppresses gonadotropin secretion, prevents luteinizing hormone surge, and inhibits ovarian steroid formation. It was found in controlled clinical trials to relieve breast pain and tenderness in the women treated considerably [6]. So in this study, the effectiveness of Danazol on benign breast disease and its side effects to be studied.

## MATERIALS AND METHODS

This was a prospective study. It was carried out following the approval from the institutional ethics committee (IEC). 92 patients of benign breast disease (BBD) were taken as study population. All the patients with complains of pain and lump in the breast with diagnosed case of benign breast disease in OPD or admitted in Department of General Surgery, M.K.C.G. Medical College & Hospital, Berhampur, were taken into consideration for the study period from July 2017 to June 2019.

### Inclusion criteria

All the female patients with complaints of pain and lump in the breast or diagnosed case of benign breast disease. All consecutive cases who attended OPD and Emergency department in M.K.C.G. Medical College & Hospital, Berhampur.

### Exclusion criteria

Patients taking hormone therapy for >6 months. Any female patient presenting with clinical picture suggestive of benign breast disease (lump in the breast and pain) were included in the study. She was explained about the study and consent taken. Thorough history was taken, which was followed by meticulous local, general and systemic examination. They were then advised for routine blood investigations, an FNAC, Mammography & U.S.G. of breast. Then the patients diagnosed with benign breast diseases are started with tab Danazol 100 mg BD for 3 months and follow up every 4weeks from start of the medication up to 12th weeks and in 6th month. Results were recorded as per clinical examination and ultrasonography for breast lump size.

### Statistical analysis

The data was collected and compiled. It was analysed using the Statistical Package for the Social Sciences version 23.0 statistical program (SPSS Inc. Chicago). Results were evaluated and compared with other published references.

## OBSERVATION AND RESULTS

Out of 92 cases 56.5% had fibroadenoma, 34.7% had fibroadenosis, phyllodes tumour were 5.4 %, ductectasia 3.2 %. Most common benign breast disease in this study was found to be fibroadenoma followed by fibroadenosis (Table 1).

In the Table 2, no cases were seen in the age group of 0 – 10 and >50 years. The age groups 11-20, 21-30, 31-40, 41-50, had 33, 31, 17, and 11 cases, respectively. Out of 92 cases of benign breast disease, maximum number of cases i.e. (36%) was seen in the age group of 11–20. Majority of the cases i.e. 70% were seen in the age group of 11-30 years. The maximum range for the age of the patients was 47 years and minimum age was 15 years.

Out of 92 patients, 52 had fibroadenoma and 32 fibroadenosis and mastalgia 8. The fibroadenosis and mastalgia patient were under gone Danazol therapy. Among which 19 fibroadenosis and 6 mastalgia had complete elimination of nodularity and pain, 12 cases

**Table 1: Distribution of breast lesions.**

Type of lesions	No. of Cases	Percentage(n=92)
Fibroadenoma	52	56.5
Fibroadenosis	32	34.7
Phyllodes tumour	5	5.4
Ductectasia	3	3.2
Total	92	100

**Table 2: Age distribution of the cases of benign breast diseases.**

Age group (years)	No. of cases(92)	Percentage
0 – 10	0	0
11 – 20	33	36
21 – 30	31	34
31 – 40	17	18
41 – 50	11	12

**Table 3: Response to drug (Danazol 100 mg) treatment.**

Response to Danazol 100mg	No. of cases	Percentage(n=40)
Elimination	25	62.5
Decrease	12	30
No response	3	7.5
Total	40	100

**Table 4: Adverse drug reactions of Danazol (n=40).**

Side effect of Danazol	No. of cases	Percentage(n=40)
Menstrual irregularity	2	5
Weight gain	1	2.5
No complaint	37	92.5
Total	40	100

reduced in size of lump and pain, 1 fibroadenosis and 2 mastalgia cases had no response in view of lump and pain respectively (Table 3).

Only 40 patients were undergone Danazol treatment out of which, 37 cases had no complain but 2 had menstrual irregularity and 1 had weight gain (Table 4).

## DISCUSSION

All the cases of benign breast diseases studied were premenopausal female. Among the 100 cases most common lesion was fibroadenoma 52%, followed by fibroadenosis 32%, mastalgia 8%, phyllodes tumour 5%, and duct ectasia 3%. Malik et al<sup>7</sup> reported 49%, Rosen PP et al<sup>8</sup> reported 45%, Greenberg et al reported 50% of fibroadenoma. Present study incidence is consistency with Greenberg<sup>9</sup>. Phyllodes tumour incidence in the study was 5% as compared to 0.4% in Malik et al [7].

Out of 92 cases, maximum number of cases belonged to adolescent, 36% were in between 11 to 20 years, 34% cases were young adult, between age group 21 to 30 years. 18% cases belong to 31 to 40 years and 12% cases belonged to 41 to 50 years. Youngest patient was 15 years in the study and eldest being 47 years. In our study, 70% of cases belonged to adolescent and young adult females comparable to study where peak incidence of benign breast disease was between 21-30 years of age group.

The use of Danazol in a low dose, 100 mg for short duration i.e. 3 months showed very good response by eliminating nodularity and pain in 62.5% cases, decreasing in symptoms of benign breast disease in 30% of cases and no response in 7.5%. These results were comparable to a study conducted by Greenberg et al. [8-11], who found that Danazol can eliminate nodularity in 26 cases (65%), decrease nodularity in 13 cases (32.5%) and no response in 1 case (2.5%) out of 40 cases. Only 5% case of all the study population had menstrual irregularity and 2.5% developed weight gain and rest 92.5% had no side effect.

## CONCLUSION

In this present study, 92 patients of benign breast disease

were taken in to study of which 52% had fibroadenoma, 32% had fibroadenosis, 8% had mastalgia, 5% phyllodes tumour and 3% duct ectasia. Fibroadenoma are one of the most common benign tumors followed by fibroadenosis in the adolescent population. The exact etiology is unknown. However, several studies show that estrogen, progesterone, growth hormone and testosterone influences the development of benign breast diseases. Given the prevalence of benign breast disease in the adolescent population and the psychosocial morbidity of finding a mass in the adolescent breast, it is imperative for physician treating patient to be familiar and up to date with this disease process. Currently available treatment varies from observation to surgical excision. Surgery is the standard treatment of choice for fibroadenoma, phyllodes tumour.

Extensive trials with the new hormonal agent, Danazol, indicate that the pain, tenderness, and lumpiness of BBD may be eliminated or greatly reduced, lessening the urgency of surgery. The persistence of a dominant nodule after a 3-month course with this steroid could serve the surgeon well by pointing to the site where biopsy would prove informative. Danazol is a valuable addition to our therapeutic armamentarium for the conservative management of certain types of benign breast disease.

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