

Efficacy of Danazol Versus Panadol In Management Of Resistant Mastalgia

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ABSTRACT

Aim: To determine the effectiveness of Danazol versus Panadol in the treatment of mastalgia.

Study Design: Prospective Study.

Place and Duration: Combined Military Hospital, Peshawar; from February 2022 to March 2023

Methods: Total 54 women with range age 18-42 years presented in this study. Female patients of reproductive age group with moderate to severe breast pain and resistant cases (taken analgesia for 3 months) were included. Age, body mass index, place of residence, level of education and marital status were among the many comprehensive demographics obtained after receiving informed written consent from enrolled patients. Women were equally divided in two groups I received Danazol 100mg oral twice a day and group II received Panadol oral in 27 patients for 3-months. Post-treatment effectiveness among both groups was compared. SPSS 20.0 was used to analyze all data.

Results: In all 54 females, 22 (40.7%) had age 28-30 years, 18 (33.3%) cases had age 31-40 years and 14 (25.9%) cases had age 41-42 years. In group I mean BVMI was 22. 11±4.28 kg/m² and in group II mean BMI was 21.7±6.30 kg/m². We found a significantly excellent results in group I among 21 (77.8%) cases in terms of reduction in breast pain, as compared to group II in 15 (55.6%) cases with P value <0.004. Frequency of menstrual problem, weight gain and hirsutism was higher 11 (40.7%) as compared to Danazol group in 9 (33.3%) cases but did not found any significant difference.

Practical implication: Effective use of Danazol reduces the need for Panadol. Therefore, there will be a decrease in Panadol Overuse.

Conclusion: We concluded in this study that use of Danazol in the treatment of resistant mastalgia was effective and useful as compared to Panadol in terms of pain retrieve and less recurrence rate.

Keyword: Mastalgia, Danazol, Panadol, Side Effects, Recurrence, Resistance

INTRODUCTION

Breast pain, involving one or both breasts, is one of the most common and troubling issues faced by females amounting for 70% of the female population. This pain, also known as mastalgia, is encountered by females at some point in their lives¹. In our set ups, these patients are dealt by general care practitioners as well as surgeons². When breast discomfort is improperly, unnecessarily, or incompetently managed, it places a heavy burden on both individuals and the healthcare system. One of the most common social taboos faced is the belief that this may be initiation of a cancer pertaining to breast³ and this is the worst situation a patient can be in. Fear of breast cancer is mostly the reason patients report to clinics for expert advice⁴.

Numerous medications have been used in an effort to control this problem, including progesterone, bromocriptine, testosterone, or oestrogen to regulate hormone production, although there is no strong evidence to support their use⁵. Currently, the most successful method of treating cyclic mastalgia and PMS is suppression/elimination of the ovarian cycle, which may be accomplished with high dosage oestrogen, continuous combination oral contraceptive use, GnRH and Danazol. Use of combination oral contraceptive tablets has produces clear findings that oestrogen increase the risk of endometrial contraceptive tablets has produced clear findings that oestrogen increase the risk of endometrial hyperplasia. Although GnRH agonists are effective, the side effects and menopause symptoms they cause are unacceptable for prolonged usage. Danazol has promising results in the short-term treatment of cyclic mastalgia in clinical trials. There may be associated speaking issues because of changes in voice, increased weight, hirsutism, changes in menstrual cycle and skin issues like acne⁶⁻⁸.

Most cases of breast discomfort they are not associated with menstruation are classified as "non-cyclic" meaning their origin is unclear, but are thought to be anatomical rather than hormonal.

About 16% of women on oestrogen and 32% of women taking combined hormonal therapy report experiencing breast discomfort. Non-medical management involves using well-fitted bras, management of dietary intake including fat restriction, optimization of body temperature, counselling of the patient and abstinence from methyl xanthine use⁹. Moreover, there have been various medicines that have been used to manage mastalgia¹⁰. Danazol acts specifically on the pituitary-ovarian axis, making it an antiGonadotrophic. Historical, this medicine has been the go-to for treating benign breast disease, as its designation as an impending androgen.

The purpose of this research was to compare the efficacy of Danazol and Panadol in the treatment of mastalgia.

MATERIAL AND METHODS

This prospective study was conducted at Combined Military Hospital Peshawar from April 2022 to June 2022 after permission from Ethical Review Board of the Institution and comprised of 54 women. Age, body mass index, place of residence, level of education and marital status were among the many comprehensive demographics obtained after receiving informed written consent from enrolled patients. Patients who had district lumps, nipple discharge, breastfeeding pregnancy or breast abscesses were not included in the research.

Female patients of reproductive age group with moderate to severe breast pain and resistant cases (taken analgesia for 3 months) were included. Following an accurate history taking, patients had a thorough clinical examination, which included bilateral breast palpation per standard protocol and ultrasound for cases. Women were equally divided in two groups. 27 cases of group I received Danazol 100mg oral twice a day and group II received Panadol orally in 27 patients for 3-months. We kept track of any symptoms or adjustment. The degree of discomfort in the breast was measured using a visual analogue scale. Patients using the medication for mastalgia were given a pain chart, which they were instructed to fill up daily. Following up with our patients at 4, 8 and 12 weeks for evaluation was strongly recommended. The reduction of breast pain was seen as the primary result of

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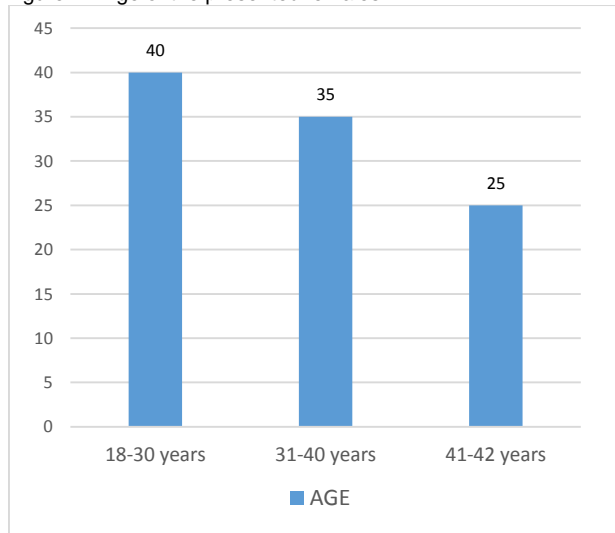
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interest. Mastalgia severity was measured using a VAS, VAS is often represented by a 10 cm long horizontal line with a word or phrase at either end. To indicate where they are experiencing pain, patients place a marker on the scale below. By measuring the distance in millimeters from line's left end to the spot the patient indicates, a VAS score may be calculated. Everything was put via SPSS 20.0 for analysis. Statistics based on frequency and percentage were applied to categorical data. All data was presented using the mean and standard deviation.

RESULTS

In all females, 22 (40.7%) had age 18-30 years, 18 (33.3%) cases had age 31-40 years and 14 (25.9%) cases had age 41-42 years. (Figure 1).

Figure -1: Age of the presented females.



In group I mean BMI was 22.1 ± 4.28 kg/m² and in group II mean BMI was 21.7 ± 6.30 kg/m². Majority of the cases in both group had cyclic mastalgia 21 females in group I and 19 cases in group. There were 16 cases in group I and 14 cases in group II had urban residency (Table 1)

Figure-2: Post-treatment outcomes among both groups



Table-1: Details of the enrolled cases

Variables	Group I	Group II
Mean BMI (kg/m ²)	22.1 ± 4.28	21.7 ± 6.30
Type of Mastalgia		
Cyclic	21 (77.8%)	19 (70.4%)
Non-Cyclic	6 (22.2%)	8 (29.6%)
Residency		
Rural	16 (59.3%)	14 (51.9%)
Urban	11 (40.7%)	13 (48.1%)

We found a significantly excellent result in group I among 21 (77.8%) cases in term of reduction in breast pain, as compared to group II in 15 (55.6%) cases with p value <0.004 (Figure 2).

Follow up taken at 7th, 30th and 90th day, we found significantly reduction in pain score in group I as compared to group II with p value < 0.005 (Table 2).

Table 2: Follow up

Variables	Group I	Group II
Mean Pain Score		
7 th day	6.4 ± 2.11	7.3 ± 1.9
30 th day	3.1 ± 1.6	5.4 ± 4.13
90 th day	0.88 ± 1.2	3.7 ± 5.8

Frequency of menstrual problem, weight gain and hirsutism was higher in Danazol group as compared to Panadol group. (table 3)

Table -3: Association of Side Effects

Variable	Group I	Group II
Side Effects		
Yes	0	6 (22.2%)
No	27 (100%)	21 (77.8%)

Recurrence rate in Panadol group was higher 11 (40.7%) as compared to danazol group in 6 (22.2%) cases but did not found any significant difference. (table 4)

Table-4: Frequency of recurrence rate among both groups.

Variables	Group I	Group II
Recurrence Rate		
Yes	11 (40.7%)	9 (33.3%)
No	16 (59.3%)	18 (66.7%)

DISCUSSION

Women 15 to 42-year age are more susceptible to develop breast discomfort. Women, who are healthy, reporting to clinics with mastalgia for advice account for two-thirds of the female population¹¹ Intense debate surrounds the optimal main treatment for breast discomfort. Danazol is a synthetic form of testosterone that act by binding to both progesterone and androgen receptors; however, it is not understood how exactly this compound alleviate mastalgia symptoms

Use of Danazol was first brought into use and marked improvement was seen in women who presented with breast pain. This was studied by Greenblatt et in females who were using Danazol for the treatment of endometriosis in 1971¹². Approximated 80% of patients who took Danazol in ranging between 100 to 400 mg daily for 3 to 6 months for benign breast disease reported complete remission of pain and nodularity.

Cyclic (related with menstrual cycles) and noncyclic mastalgia may have equally debilitating effects on women. Mammography done frequently on a patient results in mastalgia that occurs in a cyclic pattern and this may continue for over a week in each cycle if the symptoms are severe¹³.

Our study was conducted on 54 female patients out of which 22 (40.79%) had age between 18-30 years, 18(33.3%) cases had age between 31-40 years and 14 (25.9%) cases had age between 41-48 years. The results of our study, however, were in line with the previous study¹⁴. Multiple approaches are used to alleviate breast discomfort today, but most are inadequate. The purpose of

this research was to examine the efficacy, compliance, and side effects of medication used to treat breast pain in female patients. Danazol and Panadol were the two medications utilized for this study. Results were significantly good in group I (21 (77.8%) cases) in terms of reduction in breast pain as compared to group II (15 (55.6%) cases) with p value <0.004. These results of our study were also in accordance with the previous studies^{14,15} In a study conducted by Doberl et al. over a time span of six months, Danazol showed a marked reduction in VAS scores for mastalgia.¹⁶ The majority of those who took Danazol had a 1pt substantial improvement (p0.005) Both weight gain and menstrual regularity were modest. Although adverse effects limit the use of Danazol on a wider scale, Danazol is the best treatment for managing severe mastalgia and nodularity (in previous study) with a success rate of around 75%^{17,18}.

Frequency of menstrual problem, weight gain and hirsutism was higher in pa group as compared to Panadol group. Side effects included an increase in weight, skin issues like acne, oily hair and skin, nausea, hirsutism, headache, speaking issues (changes in voice due to androgens) and irregular menstrual cycle, according to a research conducted by Dhar et al.¹⁹ Recurrence rate in Panadol group was higher 11 (40.7%) as compared to Danazol group in 9 (33.3%) cases. We conducted study on resistant mastalgia which is no conducted yet. Previously researches on mastalgia were conducted between comparison of analgesia, Danazol and tamoxifen.

CONCLUSION

We concluded in this study that use of Danazol in the management of mastalgia resistant was effective and useful as compared to Panadol in terms of pain reduction this study is to see. Side effects of Danazol groups was higher.

Conflict of interest: Nothing to declare

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