

Original Research Article

Evaluation of a structured patient education protocol to achieve symptomatic pain relief and reduction in anxiety in patients with mastalgia: a randomized controlled trial

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ABSTRACT

Background: Mastalgia is the most common presentation to Breast Clinics, reassurance forms the first line of management. No studies have explored structured patient education in mastalgia till date.

Methods: Patients with mastalgia for more than 1 month were randomized to structured patient education and reassurance group. The structured patient education format was designed by the principal investigator and validated by 3 subject experts. Both the groups were assessed with visual analog scale (VAS) for pain, 12-item short form health survey (SF-12) for quality of life and generalized anxiety disorder-7 scale (GAD-7) for anxiety at baseline, 4 and 12 weeks after intervention. The assessor was blinded.

Results: A total of 64 patients were randomized equally into two groups. Both groups showed improvement in pain and anxiety scores over time. A statistically significant improvement in the SF-12 physical component summary (PCS) was observed in the structured education group at 12 weeks ($p=0.032$). Improvements in mental component summary (MCS) and GAD-7 anxiety scores were observed in both groups, but without statistically significant difference. Analgesic use decreased in both groups, with a trend toward greater reduction in the structured education group.

Conclusions: Structured patient education improves the physical component of quality of life in women presenting with mastalgia and may contribute to better overall symptom control compared to routine reassurance alone. While both interventions reduce pain and anxiety, structured education provides a standardized and potentially more effective approach to patient counselling.

Keywords: Cyclical Mastalgia, Health related quality of life, Mastalgia, Patient education

INTRODUCTION

Mastalgia is one of the most common presentations to the surgical outpatient department and breast clinics. It is frequently experienced by women of all age groups. Among the Indian population, mastalgia remains one of the major breast-related complaints.¹ Mastalgia can be cyclical or noncyclical, intermittent or continuous, and localized or generalized. The aetiology of mastalgia

is multifactorial, and the majority of cases still do not have an identifiable, specific cause despite extensive radiological imaging.² Noncyclical mastalgia is mostly seen in older women and is more commonly associated with positive findings on imaging.

Because the breast is an important organ for a woman, its discomfort draws significant attention. Misconceptions regarding the pain mostly surround breast cancer, creating anxiety and other psychological problems that

further exacerbate the symptom. Studies have proven that mastalgia negatively affects the quality of life and increases anxiety scores in both Western³ and Asian populations.¹ Although reassurance is recommended as the primary treatment⁴, no studies have explored the efficacy of a structured patient education program.

Structured patient education has been found useful in various conditions, such as type-1 diabetes, peripheral arterial disease and trauma.⁵⁻⁷ Following a structured patient education protocol designed to address various aspects of mastalgia and dispel its association with breast cancer is expected to produce a remarkable difference in treatment outcomes compared to non-structured reassurance. Hence, this study intends to compare structured patient education with classical reassurance as a 1st-line management strategy in women presenting with mastalgia, and to evaluate its effects on pain, anxiety, and quality of life. Furthermore, we intend to compare outcomes in cyclical versus noncyclical mastalgia owing to the inherent differences in their aetiologies.⁴

METHODS

This randomized-controlled, parallel-group, assessor-blind trial was conducted for a duration of 1 year, starting in August 2023, after obtaining clearance from the institutional ethics committee (AIIMS/MG/IEC/2023-24/02) and being registered under the Clinical Trials Registry-India (2022/08/057602). Patients presenting with mastalgia to general surgery outpatient department of a tertiary care centre in Southern India were evaluated for eligibility. Female subjects aged 18 years and older who presented with a primary complaint of mastalgia of more than one month's duration were included.

Exclusion criteria included pregnant women, women currently lactating during the first 6 months, participants with clinically palpable, well-defined lumps, patients who had undergone fine-needle aspiration cytology (FNAC) or biopsy within the last 7 days, patients identified with malignant or suspicious lesions, and patients with benign breast lesions (fibroadenoma, fibroadenosis, and simple cysts) detected on imaging with pain localized to those lesions. Patients diagnosed with costochondritis and those with uncontrolled hypothyroidism were also excluded.

After obtaining informed consent, baseline scores for the VAS, SF-12, and GAD-7 were recorded. Eligible patients were randomly assigned to each study group using a computer-generated block randomization list with variable block sizes of 4, 6, and 8. Allocation was concealed using sequentially numbered, opaque, sealed envelopes (SNOSE).

Patients in the experimental group (Group A) were treated with a structured education format delivered by the principal investigator, along with topical analgesia on an as-needed basis. Patients in the control group (Group B) were treated with topical analgesia on an as-needed

basis and received standard reassurance by the treating clinician. The structured patient education format was designed by the principal investigator and validated by three subject experts. It consisted of explanations regarding mastalgia types, causes, investigations used to rule out underlying pathologies (including cancer), available treatment options, and methods to allay anxieties related to breast cancer. Patients were also instructed on lifestyle modifications and how to apply topical analgesics (Annexure I).

The clinical interaction for both groups lasted at least 10 minutes. Both groups were prescribed topical analgesics (1% diclofenac gel) to be used on an as-needed basis. Patients were advised to return for strict follow-up evaluations at 4 weeks and 12 weeks using the VAS, SF-12, and GAD-7 assessment scales. The assessor (a trained nurse) was blinded, and the assessment forms contained no details regarding the patient's study group or intervention assignment.

Assessment parameters

The assessment parameters used were the VAS, SF-12, and GAD-7. The VAS scores range from 0 to 10 (with 0 representing no pain and 10 representing the worst imaginable pain) and is a reliable, valid tool for assessing pain intensity.⁸ The SF-12 is an abbreviated version of the SF-36 consisting of 12 items. It yields two composite scores: the PCS and the MCS. Each score ranges from 0 to 100, where 50 represents the average score, and scores higher than 50 indicate better physical and mental health functioning.⁹ The GAD-7 is a reliable and valid measure for anxiety in the general population. It is a 7-item scale, with each item scored from 0 to 3 based on symptom frequency over the prior two weeks. Scores of 5, 10, and 15 serve as cut-off points for mild, moderate, and severe anxiety, respectively.¹⁰

Sample size and data analysis

With an expected pre-test mean SF-36 equivalent quality-of-life score of 499 (SD=100) and a post-test mean of 554 (SD=75) among cyclical mastalgia patients with 5% level of significance and 90% power, the required sample size was calculated to be 64 using Power and Sample size calculations application version 3.1.2.¹¹

SPSS version 31 was used for statistical analysis. All categorical variables are expressed as frequencies or proportions. Data normality was assessed using the Kolmogorov-Smirnov test. Because the distribution of variables was non-normal, results are expressed as medians and interquartile ranges (Q1-Q3), and comparisons between groups were performed using the Mann-Whitney U test. The Chi-square test was used to compare pain laterality, pain cyclicity, co-morbidities, menstrual cycles, and other categorical variables between groups. The Mann-Whitney U test was used to compare age, VAS scores, analgesic requirements, and other

continuous variables between groups. Mixed effects model analysis was used for longitudinal variability. A

$p < 0.05$ was considered statistically significant.

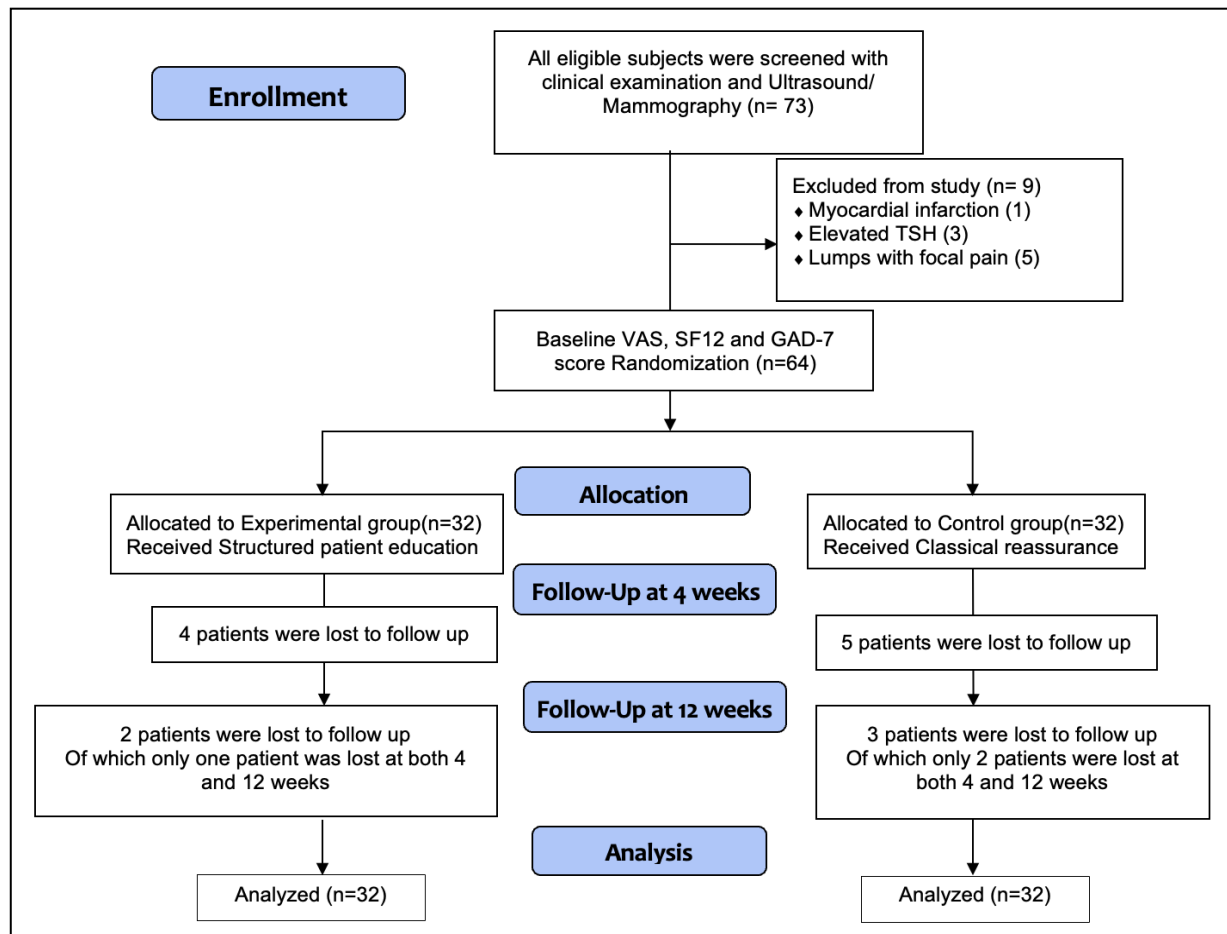


Figure 1: Consort flow diagram.

RESULTS

A total of 73 patients presented with mastalgia, of whom 9 were excluded and 64 were enrolled and randomized equally into two groups: structured patient education (Group A) and routine reassurance (Group B) (Figure 1). At 4 weeks, two patients were lost to follow-up in Group A and three in group B; at 12 weeks, an additional one and two patients, respectively, missed follow-up. All

patients were analysed using an intention-to-treat analysis. Baseline demographic and clinical characteristics were comparable between 2 groups. Average duration of symptoms was 26 months in group A and 12 months in group B. There were no statistically significant differences in baseline analgesic use, VAS scores, SF-12 PCS and MCS/GAD-7 anxiety scores between the two groups, indicating appropriate randomization and baseline comparability (Table 1).

Table 1: Baseline demographic and clinical characteristics.

Variables	Group A	Group B	P value
Age (in years), mean	43.25	40.28	0.189
Type of mastalgia (%)			
Cyclical	9 (28.1)	10 (31.3)	0.79
Non-cyclical	23 (71.9)	22 (68.7)	
Comorbidity			
None	21	20	
Present	11	12	
Duration of symptoms (%)			
<3 months	8 (25.0)	6 (18.8)	
3-6 months	10 (31.3)	13 (40.6)	
>6 months	14 (43.8)	13 (40.6)	

Continued.

Variables	Group A	Group B	P value
Menstrual pattern (%)			
Regular	19 (59.4)	18 (56.3)	
Irregular	13 (40.6)	14 (43.7)	
Parity (%)			
Nulliparous	1 (3.1)	4 (12.5)	
Multiparous	31 (96.9)	28 (87.5)	
Baseline scores (%)			
VAS	4.0 (2.5-6.0)	4.0 (2.0-5.0)	0.394
SF12-PCS	47.5 (39-53.75)	52 (40-56)	0.146
SF12-MCS	55 (46-58)	58 (53-59)	0.140
GAD 7	5 (2-7)	4 (0-8)	0.613

*VAS=Visual analog scale; SF 12=12-Item short form health survey; PCS=Physical component summary; MCS=Mental component summary; GAD-7=Generalized anxiety disorder-7 scale.

Table 2: Comparison of VAS.

Time	Group A, Median (Q1–Q3)	Group B, Median (Q1–Q3)	P value
Baseline	4.0 (2.5-6.0)	4.0 (2.0-5.0)	0.394
4 weeks	2.0 (0.0-2.0)	2.0 (0.0-2.0)	0.557
12 weeks	0.0 (0.0-2.0)	2.0 (0.0-2.0)	0.134
Change of score at 4 weeks from baseline	2.0 (2.0-4.0)	2.0 (2.0-4.0)	0.697
Change of score at 12 weeks from baseline	3.0 (2.0-4.0)	2.5 (2.0-4.0)	0.325

Pain scores (VAS)

Both groups demonstrated improvement in pain scores during the follow-up period. At 4 weeks, a reduction in VAS scores was observed in both groups, though the difference between them was not statistically significant ($p=0.557$).

At 12 weeks, further reductions in pain were observed. The median VAS score was lower in Group A than in group B, indicating greater pain improvement following structured education. However, the difference in absolute VAS scores and the change from baseline to 12 weeks did not reach statistical significance ($p=0.134$ and $p=0.325$, respectively) (Table 2).

Quality of life (SF-12)

PCS

At 4 weeks, the SF-12 PCS did not differ significantly between the two groups ($p=0.134$). At 12 weeks, however, a statistically significant difference was observed between groups ($p=0.032$), with group A demonstrating a higher PCS compared to group B (Figure 2). The change in score from baseline to 12 weeks did not reach statistical significance ($p=0.158$).

MCS

There were no statistically significant differences between groups in SF-12 mental component scores at 4 weeks ($p=0.113$) or 12 weeks ($p=0.789$) (Figure 3). However, the change in MCS from baseline to 12 weeks approached statistical significance ($p=0.057$).

Anxiety scores (GAD-7)

Both groups demonstrated mild anxiety at presentation. Anxiety scores decreased in both groups over the follow-up period. At 4 weeks, there was no

significant difference between groups in GAD-7 scores ($p=0.278$). At 12 weeks, both groups demonstrated improvement in anxiety levels, but no statistically significant difference was observed in absolute scores ($p=0.966$) or the change in score from baseline ($p=0.513$) (Figure 4).

Analgesic requirement

The requirement for topical analgesic use decreased over time in both groups. However, there was no statistically significant difference between groups at 4 weeks ($p=0.367$) or 12 weeks ($p=0.490$).

The change in analgesic usage from baseline to 12 weeks approached statistical significance ($p=0.055$).

Longitudinal variability

Further on mixed effects model analysis for longitudinal variability there was no significant difference noted between the two groups with respect to VAS (F-ratio=0.29), PCS (F-ratio=0.70), and MCS (F-ratio=0.28) of SF-12, and GAD-7 (F-ratio=0.30).

Subgroup analysis: cyclical vs. non-cyclical mastalgia

Subgroup analysis within group A and B demonstrated no statistically significant differences in improvement

between cyclical and non-cyclical mastalgia patients for pain ($p=0.45$, $p=0.75$), anxiety ($p=0.94$, $p=0.90$), or quality-of-life scores: PCS ($p=0.76$, $p=0.96$) and MCS ($p=0.07$, $p=0.78$).

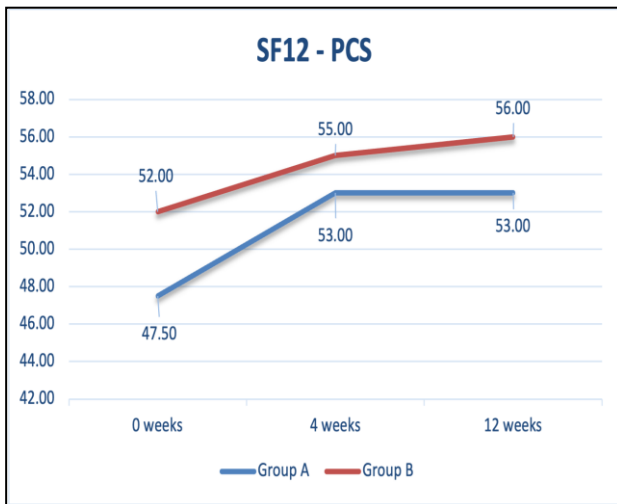


Figure 2: Comparison of PCS.

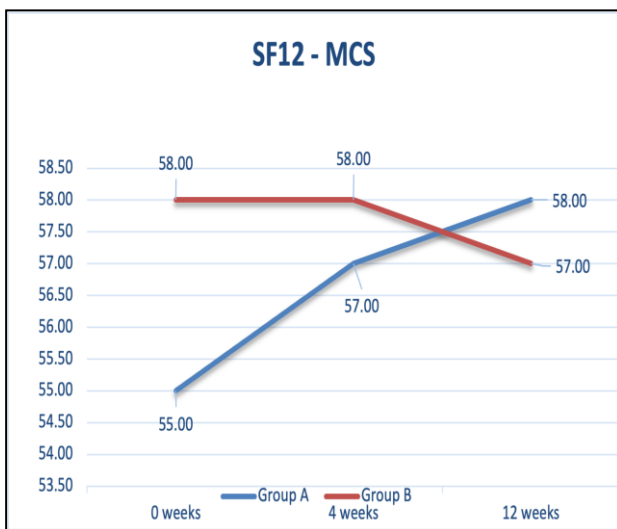


Figure 3: Comparison of MCS.

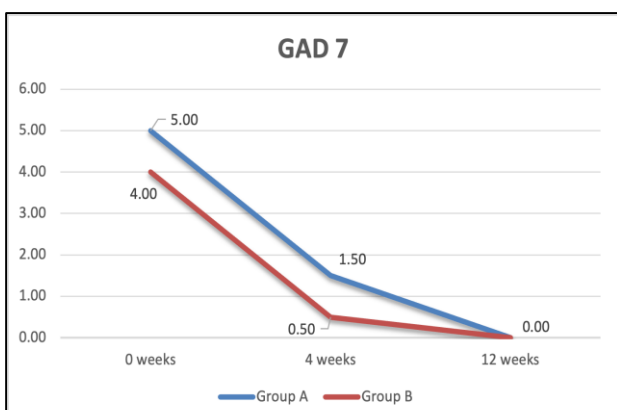


Figure 4: Comparison of GAD-7.

DISCUSSION

Mastalgia is the most frequent reason for consultation in breast clinics. Management is fraught with challenges, including varied presentations ranging from cyclical to noncyclical pain. Because the aetiology of this condition is not yet fully defined, literature on its management ranges from simple reassurance to multiple drug therapies. Although reassurance is commonly recommended as first-line management, it is rarely delivered in a structured manner. Consequently, its effectiveness varies widely and depends heavily on the quality, consistency, and clarity of communication.

Structured patient education has proven effective in various other clinical conditions.⁵⁻⁷ The findings of this randomized controlled trial demonstrate that both interventions resulted in improvements in pain (VAS) and anxiety scores over time. While mastalgia is known to negatively affect a woman's quality of life, structured patient education was associated with a significantly greater improvement in the physical component of quality of life at 12 weeks.¹² Fakhravar et al similarly reported that a healthy lifestyle promotion intervention could significantly improve the quality of life of women with cyclic mastalgia.¹³ Another notable finding over the 12-week period was the positive trend observed in the MCS of the SF-12, which approached statistical significance ($p=0.057$), indicating enhanced psychological well-being in patients receiving structured education.

Pain reduction was observed in both groups, reflecting the benign and often self-limiting nature of mastalgia. Although the reduction in VAS scores was greater in the structured education group, similar findings have been reported by Pankaj et al who demonstrated a significant reduction in mean VAS scores with successive follow-ups, suggesting that reassurance plays an important role in alleviating breast pain.¹⁴ Additionally, Roy et al reported that 67.44% of patients treated with topical NSAIDs as first-line therapy experienced complete resolution of pain; similarly, our findings indicate a reduction in the use of topical analgesics over time. Structured educational counselling may enhance patients' understanding of the benign nature of mastalgia, thereby reducing pain perception through psychological reassurance.¹⁵

Previous research in Indian populations has similarly demonstrated elevated anxiety levels among women with benign breast conditions.¹ Fear of breast cancer remains a major contributor to anxiety in patients presenting with mastalgia. In the present study, GAD-7 scores improved in both groups, indicating that reassurance alone can alleviate anxiety to some extent. KağanKatar et al reported significantly higher anxiety and depression scores in patients with mastalgia compared to controls.¹⁸ Furthermore, anxiety and depression have been shown to influence both the severity and duration of

mastalgia, creating a self-perpetuating cycle. Educational interventions that clarify the benign nature of mastalgia and explain the diagnostic process may help break this cycle by addressing underlying misconceptions. Although the difference in anxiety reduction between the two groups was not statistically significant, the observed trend toward greater improvement in the structured education group suggests that a larger sample size may reveal a more pronounced effect.

Notably, this study demonstrates that structured patient education is equally applicable to noncyclical mastalgia, as there were no significant differences in the outcome parameters between cyclical and noncyclical cohorts. This reinforces the universality of structured patient education as a first-line management protocol. It represents a low-cost, easily implementable intervention that can be seamlessly integrated into high-volume outpatient clinics to ensure uniform counselling and improve overall patient satisfaction.

Limitations

This study has several limitations. First, the relatively small sample size may limit the statistical power to detect differences in certain outcomes, particularly anxiety and pain reduction. Second, the follow-up period was limited to 12 weeks; longer-term follow-up would be valuable to assess the sustainability of these benefits. Third, the single-centre design may limit the generalizability of the findings. Future multicentric studies with larger sample sizes and extended follow-up durations are warranted.

CONCLUSION

Structured patient education improves the physical component of quality of life in women presenting with mastalgia and may contribute to better overall symptom control compared to routine reassurance alone. While both interventions are associated with improvements in pain and anxiety, structured counselling may offer a standardized, reliable, and potentially more effective approach to patient care. We recommend further studies incorporating structured patient education as it may enhance patient coping strategies and reduce clinical anxiety associated with mastalgia.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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ANNEXURE I

Structured patient education protocol for mastalgia

1. Speak to the patient regarding the severity of mastalgia and the main reason for the hospital visit is pain or anxiety regarding breast cancer?

After understanding the patient concerns and beliefs, explain regarding mastalgia according to the points given below:

2. What is mastalgia? Explain the prevalence of mastalgia in her age group.

Breast pain or mastalgia is the pain arising from breast or underlying tissue. It is a very common symptom which most of the women in reproductive age group (50-80%) complaints about. Based on its pattern it can be divided as cyclical or non-cyclical.

3. What are the common causes of mastalgia?

Causes of breast pain still remains unclear. Based on various research studies, multiple factors such as varying hormonal levels during menstrual cycle, dietary intake of certain food products (like coffee, soya), large breast size and psychological disturbances plays a role.

4. Explain about cyclical and non-cyclical mastalgia.

Cyclical breast pain is characterized by diffuse mild to moderate pain usually bilateral which increases around 1-2 weeks prior to menses. It is proposed to be mediated by hormonal changes during the cycle. Mostly there are no abnormalities found in radiological investigations.

Non-cyclical breast pain is mostly unilateral and localized to any one of the quadrants. It is mostly caused by any structural abnormalities in the breast tissue which will have some radiological finding associated with it. It can mild, moderate or severe based on the type of lesion.

5. Explain about the investigations done to rule out serious causes of mastalgia.

Initially to rule out any structural abnormalities, we will do breast imaging- Ultrasound or mammogram (based on whether the age is below or above 40). FNAC/Biopsy will be done if any mass or swelling is found palpable. Additional imaging modalities such as MRI may be used for further evaluation.

6. Explain that mastalgia is not a symptom of breast cancer and she has not increase risk to develop breast cancer.

Generally, Breast cancer is not presented with any symptoms of pain. According to studies, it is associated with only 2 to 7% of breast cancer cases, which is not considered to be significant. Also, we will be using investigations in all patients to rule out breast cancer.

7. Explain about the treatment options available and the side effects.

There are many drugs to treat mastalgia, all of them are proven to be effective. Ointments containing pain killers are the simplest and most effective treatment. Other drugs act on hormones and are required in patients with severe pain not responding to any simpler treatments. These drugs can have side effects like altering your periods and should not be taken by women expecting pregnancy. Hence, they are reserved for only patients with severe pain not responding to simpler treatments.

8. Explain about the modifications she can make to relieve pain.

Most of the pain related to breast can be treated without any medical treatment. Be confident about your pain. Reduce your anxiety by distracting yourselves in any physical activities. Wear a well fitted supportive bra. Seek medical help if it is bothering your daily activities.

9. Prescribe a topical analgesic and explain how to use it.

Explain the patient to use the prescribed topical analgesic (1% diclofenac gel) on SOS basis up to BD per day on the region she has pain.

10. Explain that the treatment is directed at pain relief and there is not underlying pathology in her breast which are dangerous or can turn malignant in future.
11. Reassure her and ask if she has any questions or anxiety regarding her symptoms. Assure her it's a safe environment to ask questions.