



Role of Reassurance and Proper Mechanical Support Advice on Quality of Life and Pain Relief in Patients of the Mastalgia-A Prospective Follow-up Study at A Tertiary Care Center in a Developing Country

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ABSTRACT

Objective: To study the effect of reassurance and proper mechanical support on quality of life (QOL) and visual analogue score (VAS) pain assessment in patients with mastalgia at a range of follow-ups.

Materials and Methods: A prospective follow-up study was conducted among women aged 15–45 years, complaining of breast pain without any abnormality detected clinically and radiologically. After consent to participate and enrollment, all the study participants were counseled and reassured about the non-neoplastic nature of the disease and about wearing proper mechanical support/Bra; this was repeated at each follow-up. VAS was used to assess the pain intensity perceived by the woman at each follow-up, post intervention. The Short Form-36 (SF-36) scale was used to evaluate health related QOL (HRQOL).

Results: Among 80 patients, 31.2% were wearing a Bra of fabric other than cotton, 21.2% were wearing a loose fit mechanical support/Brassiere, while 10% were not wearing any mechanical support at baseline. The overall mean VAS score was significantly reduced with each follow-up, indicating decreased perception of breast pain over time. There was a significant difference between the mean SF-36 score between base line and after three months ($p < 0.0001$). Mean scores in all domains of the SF-36 increased. The greatest reduction in mean VAS score was seen in 26–35 years age group and women with a body mass index $< 18.5 \text{ kg/m}^2$.

Conclusion: Reassurance and wearing proper mechanical support/Bra are effective for improving QOL and alleviating breast pain/mastalgia. These simple processes should be used for the management of mastalgia.

Keywords: Mastalgia, breast pain; quality of life; reassurance; mechanical support; body mass index

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Key Points

- Mastalgia is seen to have a connection with various conditions such as anxiety, stress, body mass index, improper diet, improper education regarding proper breast support, psychological symptoms of somatization disorders, especially where mastalgia is resistant to treatment.
- Two most common issues that trouble the patient of mastalgia are firstly, fear of suffering from breast cancer and secondly, breast pain or discomfort affecting their quality of life.
- Reassurance and wearing proper mechanical support/Bra are crucial in improving the quality of life and alleviating the breast pain/mastalgia and should be utilized by breast physicians in clinical decision making for its management.

Introduction

Mastalgia or breast pain is a very common complaint among women, especially in the reproductive age group (1, 2). It is either cyclical or non-cyclical, and when cyclical may mirror the menstrual cycle of the patient. Mastalgia may adversely affect daily life by reducing the quality of life (QOL) and lead to anxiety for the patient (3-5). Usually,

the two most common issues that trouble the patient with mastalgia are, firstly, fear of breast cancer and secondly, breast pain or discomfort affecting their QOL (6).

QOL of an individual is based on various factors, including physical, social, economical and/or mental factors. Perception of pain is one of the most prominent physical factors affecting the QOL of any

individual. Pain is a constant struggle with sensory impairment and affect the emotional state of the patient, who may have different pain tolerance, and hence react differently; this may eventually impact their QOL (7).

The prevalence of breast pain in the Indian population is 47.33% (8). The etiology of mastalgia is unclear despite the advances made in medicine. Of all the disease conditions associated with mastalgia, the most common is benign breast disease. Mastalgia has also been associated with various conditions, such as anxiety, stress, body mass index (BMI), improper diet, poor education regarding proper breast support, and psychological symptoms of somatization disorders, especially when mastalgia is resistant to treatment (6, 9, 10). In such cases, reassurance and some lifestyle modifications have been found to be effective (11, 12).

Various treatment modalities have been used and proposed to treat patients suffering from mastalgia, but reassurance and proper mechanical support has been found to be most effective (10, 13, 14). Mastalgia has been reported to affect an individual's daily activities and QOL (6, 8). It is reported that when reassured about the absence of breast cancer, almost 85% women show relief of pain and psychological stress and anxiety (11).

There is little research into this topic in the Indian population. Thus, the present study was planned with the aim of investigating the effect of reassurance and advice about mechanical support in improving the QOL and alleviating the pain of mastalgia.

Objectives: To study the effect of reassurance and advice about proper mechanical support on health-related QOL (HRQOL) at baseline and three months follow-up and to investigate pain perception [visual analogue score (VAS)] in patients with mastalgia at 15 days, and one and three months follow-up.

Materials and Methods

Study Design: Prospective follow up study.

Study Setting: Outpatients Department of Surgery of a tertiary care Centre of Lucknow.

Study Period: December 2020 and June 2022 (18 months).

Study population: All female patients presenting with breast pain in the Outpatients Department of General Surgery of a tertiary care center in Lucknow, India.

Inclusion criteria: Any female patient aged 15–45 years with breast pain was included in the study.

Exclusion criteria:

1. Females with breast pain because of inflammatory causes or any fibrocystic disease.
2. Females with breast cancer.
3. Females with congenital anomalies of the breast.
4. Females who have not yet achieved menarche.
5. Patient already diagnosed to have somatoform disorder.
6. Females refusing to participate in the study.

Sample Size: Finite Population Correction has been applied to the sample size formula

$n = N * X / (X + N - 1)$, where, $X = Z_{\alpha/2} * 2 * p * (1-p) / d^2$, $Z_{\alpha/2}$ -critical value of the normal distribution at $\alpha/2$ (for a confidence level of 95%, $\alpha = 0.05$ and the critical value is 1.96), p - Estimated sample proportion i.e., Proportion of females of reproductive age group who showed reduction in pain after using a proper fitted bra/mechanical support (value is 32%) (13), d - Margin of error for appropriate level of precision (value is 0.075), N - Estimated population size i.e. approximate frequency of reproductive age females with mastalgia attending the hospital during the study period (value is 2880). At 95% confidence interval and power of 80%, the minimum sample size would be 72 patients. However, taking 10% dropouts, the final sample size required was 80 patients.

Ethical Considerations: Ethical approval for the study was obtained from the Institutional Ethical Committee of the Tertiary Care Centre (IEC no/date: 83/21 - Dr. Ram Manohar Lohia Institute of Medical Sciences).

Data Collection Procedure

Any female patient presenting with complaints of breast pain and with no abnormality detected in physical, radiological and histological examination and fulfilling the inclusion criteria was invited to participate. After giving informed written and verbal consent, the VAS was explained to them. This was followed by obtaining a detailed history which included breast pain history (duration of symptoms, cyclical, or non-cyclical) and concluded with a physical examination. Appropriate investigations (ultrasound of both breast and axilla, mammography and fine-needle aspiration cytology) was advised as per symptoms and signs. A pretested, predesigned proforma was used to record relevant information from each individual patient.

Reassurance was given by counseling that symptoms were not associated with any major or serious breast conditions, including cancer. Reassurance was reinforced by describing the normal findings from investigations. After reassurance, the female was counseled regarding wearing a proper fitted mechanical support/Bra, including advice about comfort, adequate fit, good support, and ideal fabric. Fabric preference was cotton over other fabrics due to its non-stretchability, being good for sensitive skin, absorbance of sweat so lowering infection risk, provision of skin breathability and provides firm support. The right size was identified using the bra size chart and measuring the over and under bust size in centimeters. The right strap is the one that sits over the shoulder perfectly, doesn't dig in the skin or fall off shoulder. The right band sits perfectly around the rib cage and should form a level straight line around the torso. The cup should snug the breast covering the front and sides of the breast.

All patients were followed-up at 15 days, and one and three months post intervention. At every visit, VAS score was assessed, breast support and breast pain chart were checked, and data was recorded on a predesigned proforma and counseling was repeated.

Short-Form Health Survey (SF-36)

The HRQOL of the patients was evaluated by the SF-36 scale. The questions were converted into Hindi and then the patients were asked to mark their answers. The SF-36 scale consists of 36 items consisting of eight subscales, which includes physical role due to emotional issues and functioning, general health, bodily pain, vitality or energy, mental

and social health. Maximum score is 100, and the obtained scores vary between 0 and 100 scores for each subscale. Higher scores imply good physical and mental health where as a low score signifies deteriorated health. SF-36 is a commonly used tool to measure HRQOL (15).

Statistical Analysis

The data was analyzed using SPSS, version 24.0 (IBM Inc., Armonk, NY, USA). Descriptive summary using frequencies, percentages, graphs, mean, and standard deviation was used to present study results. Probability (*p*) was calculated to test statistical significance at the 5% level of significance. The statistical test for comparison of mean VAS score at each follow up was done using the repeated measures ANOVA test.

Results

More than half (58.8%) were wearing cotton mechanical support/Bra, while 31.2% were wearing a Bra of other fabric and 10% were not wearing any mechanical support. When bra fit was investigated, 45% females were wearing a normal fitting bra, 23.8% were wearing a tight fitting bra while 21.2% were wearing a loose fitting bra (Table 1).

The overall mean VAS score reduced with each follow up thereby decreasing the breast pain. There was a significant statistical difference among the mean VAS score between baseline and follow-up (*p*<0.0001) (Table 2).

The overall mean SF-36 was significantly higher at the third follow up when compared to the baseline indicating a perceived improvement in the HRQOL (*p*<0.0001) (Table 3). At baseline the scores indicated poor HRQOL in all the domains of the SF-36 score with very low values in domains like physical role, pain, general health and emotional role difficulty. There was a significant increase in the mean scores in all the domains of SF-36 scale (Table 4).

VAS scores varied with both age of the respondents and their BMIs. In terms of age grouping, there was a significant difference in the mean VAS score at first, second and third follow up (*p*<0.05). The mean VAS

score after three months was 2.17±1.19, 2.36±0.67 and 1.80±0.64 among 15–25, 26–35 and 36–45-year-old women, respectively. Maximum reduction of VAS score occurred in the 26–35 years age group from baseline, as shown in Figure 1.

There was a significant difference in the mean VAS score at first, second and third follow-up (*p*<0.05) in terms of BMI grouping. The mean VAS score after three months was 2.00±0.0001, 2.10±0.9, 1.94±0.6 and 2.32±0.75 among females with BMI <18.5, 18.5–22.9, 23–24.9 and ≥25 kg/m², respectively with maximum reduction of VAS score among females with BMI <18.5 kg/m² from baseline, as shown in Figure 2.

Discussion and Conclusion

Mastalgia among women may be very painful and can account for 80% of breast complaints referred to the outpatient department. It is an entity largely ignored both scientifically and clinically. The two most common concerns of patients presenting with mastalgia are the fear of breast cancer and the presence of severe pain affecting their QOL (13). Mastalgia negatively affects a women’s QOL (15). Most patients with mastalgia can be managed well with reassurance and after receiving advice about wearing proper mechanical support or a bra, the HRQOL improves. The present study prospectively assessed women with mastalgia and concluded that reassurance and advice on wearing a well-fitted and supporting bra played a significant role in alleviating their pain.

The study observed a significant decrease in breast pain of the study participants following repeated counselling for wearing a proper fitted bra and reassuring them regarding the natural history and possible causes of symptoms and non-neoplastic nature of the current symptoms. This was reflected in their mean VAS score which reduced significantly at each follow up indicating the alleviation in breast pain. The scientific evidence behind wearing a proper mechanical support bra is that active breast movement on its weak suspensory ligaments contributes considerably to mastalgia, so good external support by a proper fitted bra relieves most of the patient’s symptoms (13).

Similar findings were reported by Hafiz et al. (12) that reassurance plus bra-fitting advice provided relief for most women. If symptoms persist, the addition of topical non-steroidal anti-inflammatory drugs (NSAIDs) provides relief in 70–92% of women. In a systematic review by Kataria et al. (16) it was reported that up to 70% of women wear improperly fitted bras. Thus, it is important to ensure that the patient is fitted with sufficiently supportive and well-fitting brassiere. It is especially useful in women endowed with large breasts.

The QOL assessed using the SF-36 was significantly higher at the third follow-up when compared to baseline, which indicates improvement in the HRQOL. At baseline the QOL was poor in all the subscales of the SF-36 score, especially emotional health, role limitations as a result of physical health, localized pain and general health. However, significant improvements were seen in all subscales over the duration of the study.

Table 1. Distribution of study participant on basis of fitting of mechanical support/bra at the first visit (n = 80)

Parameter	Class Interval	Frequency	Percentage
Fabric	Cotton	47	58.8
	Other	25	31.2
	Not wearing	8	10.0
Fitting	Tight fit	19	23.8
	Normal Fit	36	45.0
	Loose Fit	17	21.2
	Not wearing	8	10.0

Table 2. Mean VAS score of the study participants at various follow ups

Parameter	Baseline	First follow-up	Second follow-up	Third follow-up	f-value	<i>p</i>
VAS score (n = 80)	5.96 ± 0.83	5.11±1.14	3.89±0.81	2.13±0.77	832.671	0.0001
VAS: visual analogue score						

A few similar studies have been done on patients with mastalgia and their QOL. Saeed and Ali (7) studied the impact of psychological intervention on QOL in patients of mastalgia. Prior to psychological interventions, there was no significant difference in both groups in SF-36 scale. However, after psychological intervention, the participants in Group I who received psychological interventions had significantly higher scores on all sub-scales of SF-36 (7).

Similar to our study, Kannat et al. (6) found that the QOL of patients with mastalgia was lower than that of the control group, and the sub scales of physical function ($p = 0.04$), body pain ($p = 0.02$), general health ($p = 0.03$), and energy ($p = 0.008$) were significant.

A study compared the QOL amongst eastern and western populations in Turkey. According to SF-36 results, the mean score of physical, physical role difficulty and social functions were found to be lower in the eastern group than in the western group ($p = 0.029$, $p = 0.002$, and $p = 0.001$, respectively). The mean scores in both groups were similar to the baseline mean SF-36 scores subscales of the present study (15). These studies did not evaluate the pre-post change in the SF-36 score after intervention.

The present study observed maximum reduction in mean VAS score at three months post intervention. Hadi (13) conducted a randomized trial in 200 women with mastalgia, where 100 women received treatment with danazol and the other 100 were asked to wear sports bras for 12 weeks. In the danazol group, 58% reported relief of symptoms (with drug side effects in 42%), while in the bra group, 85% had relief of symptoms. Sports bras have a proper mechanical support and fit which can relieve pain by reducing the overstretching of the Cooper’s ligament (13).

Age and BMI of the female was also a significant predictor of improvement in the pain of mastalgia. The present study observed a significant statistical difference in the mean VAS score across various age groups and across different BMIs at each follow up. Maximum

reduction in mean VAS score was seen in 26-35 years age group and those females whose BMI was less than 18.5 kg/m². This finding was similar with the study by Kocoglu et al. (12) who observed that age and BMI are important determinants of mastalgia. Other researchers have also concluded that age and BMI are important variables in the management of mastalgia (4, 10). However, our findings are contrary to the study by Raghunath et al. (8) who observed that women with low BMI had higher risk for mastalgia as compared to those with normal BMI (RR = 1.063) or high BMI (RR = 1.685) and hence improvement of pain also varied accordingly (7). This is attributed to the fact that BMI, mastalgia and psychological stress are very well correlated, and this parameter was not seen in our study.

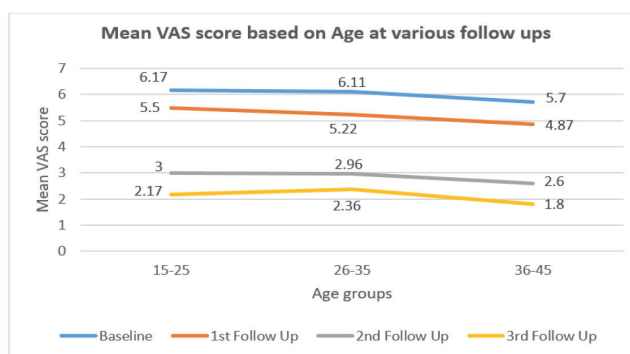


Figure 1. Mean VAS score based on Age at various follow ups

VAS: visual analogue score

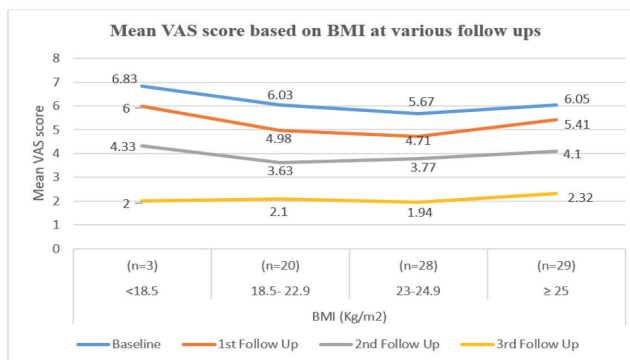


Figure 2. Mean VAS score based on BMI at various follow ups

VAS: visual analogue score; BMI: body mass index

Table 3. Mean SF-36 score of the study participants at various follow ups

Parameter	Baseline	Third follow-up	t-value	p
SF-36 score (n = 80)	58.64±13.45	88.27±10.21	15.694	<0.0001

Table 4. Mean subscales of SF-36 score of the study participants at various follow ups

Sub-scales of SF-36	Baseline	Third follow-up	t-value	p
Physical functions	72.17±12.69	92.28±5.86	12.868	<0.0001
Physical role	45.51±21.46	88.51±12.89	15.363	<0.0001
Pain	52.05±15.87	87.47±9.97	15.495	<0.0001
General health	54.07±12.36	87.55±11.58	18.098	<0.0001
Vitality (Energy)	59.74±17.21	91.75±10.38	14.246	<0.0001
Social function	66.39±13.76	93.86±12.85	13.050	<0.0001
Emotional role difficulty	49.71±19.27	81.68±14.27	11.925	<0.0001
Mental health	57.47±15.02	86.12±13.71	12.601	<0.0001

Study Limitations

The study has some limitations. Firstly, there was no control group and hence it was difficult to ascertain any association of age and BMI with the improvement of symptoms. Secondly, randomisation was not performed so there is a risk of selection bias. Still, our study gives useful insight into the importance of reassurance and wearing proper mechanical support in the alleviation of breast pain/mastalgia and its effect on HRQOL, pre- and post-counseling. Further clinical trials on a larger sample will be beneficial in generating more evidence to include this intervention in regular clinical practice of breast physicians.

Reassurance and wearing a proper mechanical support appear to be important in reducing the pain of mastalgia with maximum alleviation of pain at three months. HRQOL was significantly improved after counseling in patients with mastalgia. Age and BMI were significant factors in receiving alleviation in pain after the intervention and should be considered by breast physicians in clinical decision making.

Ethics Committee Approval: Ethical approval for the study was obtained from the Institutional Ethical Committee of the Tertiary Care Centre (IEC no/date: 83/21 - Dr. Ram Manohar Lohia Institute of Medical Sciences).

Informed Consent: Informed was written and verbal consent.

Peer-review: Externally and internally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: H.P., P.R., A.S.; Concept: H.P., P.R.; Design: H.P., R.S.; Data Collection or Processing: H.P., R.; Analysis or Interpretation: H.P., S.S.; Literature Search: H.P., A.S., S.S.; Writing: H.P., P.R.

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