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Prevalence and predictors of Anxiety and Depression in Patients Presenting to Breast Services

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Title Page

Title – Prevalence and predictors of Anxiety and Depression in Patients Presenting to Breast Services – a cross sectional study

Running Title - Anxiety and Depression in Breast Services' Patients

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Abstract

Background: Studies show that anxiety and depression are very common across patients presenting to outpatient services for medical illnesses. We expect similar or even higher prevalence in patients with breast complaints, owing to vitality of breast in terms of sexuality, identity and confidence. Thus, this study was proposed to estimate the prevalence and identify risk factors for anxiety and depression in patient's seeking breast services.

Methods: We have conducted a descriptive cross-sectional study among patients seeking breast services of a tertiary care centre in Western India. Data were collected by face-to-face interviews using the validated Generalised Anxiety Disorder 7 and Patient Health Questionnaire 9 scores

Results: A total of 215 patients were screened and 192 consenting patients were enrolled. The prevalence (95% Confidence intervals) of those at risk for anxiety requiring further clinical evaluation was 46.4% (39.2%, 53.7%) and it was 29.7% (23.3%, 36.7%) for those at risk for major depression that warrants further clinical evaluation by a mental health provider. The predictors (aOR; 95% CI; *P* value) of anxiety were age (1.053; 1.024, 1.083; p<0.001) and post-menopausal status (2.475; 1.200, 5.103; p=0.014). The predictors (aOR; 95% CI; *P* value) of depression were age (0.954; 1.927, 0.981; p=0.001) and Rural place of residence (2.362; 1.023, 5.433; p=0.044).

Conclusions:

There is a high prevalence of those at risk for anxiety and depression among patients who seek breast services. The predictors for those at risk for anxiety were higher age and post-menopausal status and for those at risk for depression was young age and women

residing in rural areas.

Keywords:

Breast services, Anxiety, Depression, Generalised Anxiety Disorder scale - 7, Patient Health Questionnaire - 9

Strengths:

- It has a sufficiently large sample size and does not differentiate based on the final diagnosis (benign or malignant).

Limitations:

- Since it was not a cohort study, the diagnosis whether benign or malignant was not known which could have further caused changes in mood.
- The actual prevalence of anxiety and disorder could not be ascertained as their status of evaluation by a mental healthcare provider was unknown. Only "at risk" individuals were identified.
- It is a single centre study and hence the results may not be generalizable to the entire state or the country.

Introduction:

Depression, anxiety, and substance abuse are the commonest yet often missed psychiatric illnesses in non-psychiatric outpatients [1,2] and the lifetime prevalence of depression and generalized anxiety disorder (GAD) is 12.1% and 3.7% respectively. [3,4] As psychological factors are increasingly recognized as determinants of therapeutic progress, the psycho social and cultural needs of patients ought to be considered more so because quality of life (QOL) has shown to be an independent predictor of disease related outcomes. [5] However, the first step towards targeting mental well-being as a part of comprehensive care, is to identify the problem, via patient screening, and determine the presence of anxiety and/or depression which are missed out on routine clinical assessment.

Breast related symptoms are expected to elicit anxiety and/or depression, owing to the various fear generated in a woman – of cancer, losing a vital sexual organ, rejection by family or social out casting, in addition to that of expenses, hospitalization, and surgery. For instance, Scurr et al from United Kingdom reported that among women with mastalgia, over 40% had decreased sexual activity, 35% had disturbed sleep, and 5% reported effects on work activity. [6] Similarly, a meta-analysis of 36 studies that included 16,298 breast cancer patients between 2000 and 2018 estimated the prevalence of anxiety to be at 41.9% [95% confidence interval (CI): 30.7, 53.2] [7] The prevalence of depression was said to be 10–25% of patients diagnosed with breast cancer. [8] Thus, it becomes important to understand the burden of anxiety and/or depression in this group of patients. A thorough literature search in English language, found that only very few studies had been conducted to estimate the prevalence of psychiatric illnesses in breast outpatients, inclusive of patients with benign

breast conditions as most studies were conducted among breast cancer patients and the data from India was also meagre. Hence the objective of this study was to determine the prevalence and predictors of anxiety and depression in patients presenting to the breast services of a tertiary care center in Western India using standard validated scales such as the Generalized Anxiety Disorder Scale-7 (GAD-7) for anxiety and Patient Health Questionnaire-9 (PHQ 9) for depression.

Methods:

Ethics:

The research received authorization from the Institutional Ethics Committee at the hospital where it took place, identified by reference number EC/OA-181/2020, dated 19.02.2021. Before joining the study, all potential participants provided written informed consent. The research adhered to the principles of Good Clinical Practice outlined in the Declaration of Helsinki (World Medical Association, Fortaleza, 2013) and followed the National Guidelines for Ethical Research in Human Participants (Indian Council of Medical Research Guidelines, 2017)

Study Design and Setting:

A descriptive, cross-sectional study was conducted between 20th February 2021 and 15th June 2021 in a public tertiary care teaching hospital from a metropolitan city, Mumbai of Western Indian. The hospital is run by the civic body – Brihanmumbai Municipal Corporation and it caters predominantly to the low- and middle- income people at a highly subsidized cost.

Study Sample:

All female patients 18 years and above with no history of dementia or lack of insight, who

attended the breast services for any breast related complaints were included in the study. Those who did not provide written informed consent were excluded from the study.

Variables:

The dependent variables of interest were the GAD-7 and PHQ-9 scores. The predictor (independent) variables of interest were age, menopause status, place of residence, education, occupation, marital status and presenting complains (Single breast-related symptom *vs* more than one)

Study Procedures:

After obtaining written informed consent, data were collected by face-to-face interviews using freely accessible universal questionnaires namely GAD-7 and PHQ-9. In addition, following demographic characteristics namely age, menopausal status, place of residence, marital status, education level and occupational status were recorded in a case record form. The clinical data including presenting symptoms were also recorded. Those who were identified at risk for anxiety and major depression requiring further evaluation by a mental health professional were referred to a certified counselor who was available as a part of breast services team. The patients/ participants were not involved in the design, or conduct, or reporting, or dissemination plans of our research

Data sources and measurements:

Demographics and clinical characteristics were elicited based on patient history. Anxiety was evaluated using the GAD-7 scale. It is a 7-item, self-rated scale developed as a screening tool and severity indicator for generalized anxiety disorder. [9] Scores range from 0 to 21 with higher scores indicating more severe GAD symptoms. While screening, a cut-off score of 10

was identified as the optimal point for risk of anxiety warranting further clinical evaluation. It has a high sensitivity (89%) and specificity (82%) as screening at this cut-off point. At follow-up, scores of 5, 10, and 15 are interpreted as representing mild, moderate, and severe levels of anxiety. [10]

Depression was evaluated using the PHQ-9 which is a self-administered depression module. [11] It is a nine-item scale representing the DSM-IV criteria from major depression with each symptom criteria being scored as a Likert from 0 (not at all) to 3 (nearly every day) [12] A PHQ-9 score ≥10 had a sensitivity of 88% and a specificity of 88% for major depression that warrants further clinical evaluation by a mental health provider. PHQ-9 scores of 5, 10, 15, and 20 represent mild, moderate, moderately severe, and severe depression, respectively. [12] The validated translations of both GAD-7 and PHQ-9 questionnaires in local languages *viz* Hindi and Marathi that are freely available online were used in this study.

Bias:

Response biases such as social desirability (SDR) and acquiescent (ACQ) responding are well known in the setting of a self-reported psychometric scales that uses Likert scale. [13] SDR stands for the inclination to react in a way that aligns with what is considered favorable by salient others, while ACQ signifies the inclination to favor the positive end of the rating scale, regardless of the item's content. [13] An attempt to mitigate the bias was done by anonymizing data collection and permitting self-administration of the questionnaires in the language of their own understanding if the participant was a literate. Similarly, referral bias due to referral of a particular group of patients based on the variables of interest [14] was negligible as the study was conducted in the general surgery department where all patients

requiring breast services irrespective of their psychological state took treatment from.

Sample Size Estimation:

Assuming prevalence of depression and/or anxiety in patients seeking breast services, at a similar rate as seen in the general Indian medical outpatients, an estimated prevalence (p) of 39.3% was considered. [15] The sample size estimated using the Cochran's formula [$Z_\alpha^2 p(100-p)/d^2$], [16] assuming a relative precision (d) = 20%, alpha error = 5% (corresponding Z score = 1.96 $\approx$ 2), power of the study to be 80%, was n = 154. We decided to increase the same by 30% to N = 192 accounting for non-responders, and cognitive and response bias due to the sensitive nature of the study measures.

Data management:

Information was initially gathered using a pen and paper format on a case record form, which was subsequently converted into digital format using Microsoft Excel (Publisher: Microsoft Corporation, Redmond, Washington, USA, 2016). Stringent measures were taken to ensure the confidentiality of patient data. Participant files were securely stored in locked cupboards, and digital data was safeguarded on password-protected computers. The analysis was conducted solely on data that had been deidentified and coded in a reversible manner. Statistical analysis was performed using Statistical Product and Service Solutions (SPSS) for Windows, Version 25.0 (Publisher: IBM Corp., Armonk, New York, USA, 2017).

Statistical analyses:

Demographic and clinical characteristics were presented as mean with standard deviation (SD) for age, and frequencies and percentage for rest of the data. A score of $\geq$ 10 in GAD-7 or PHQ-9 at screening were considered as those at risk for anxiety and major depression

warranting further clinical evaluation. The prevalence was represented as proportions with 95% CI. Univariate and Multivariable analysis to identify the predictors of anxiety and depression was conducted using the binary logistic regression. All hypothesized predictors whose p value < 0.2 in the univariate analyses alone were included in the multivariable analysis. The level of significance for all analyses was set at $p < 0.05$.

Results:

Demographic and Clinical Characteristics

A total of n = 208 patients were screened and N = 192 provided consent. The mean (SD) age of our study participants was 38.7 (11.8) years and most of them were from the age group of 18-44 years (64.6%, n = 126/192). A total of 75.5% (n = 145/192) patients were premenopausal and 84.4% (n = 162/192) were residing in urban areas. Clinically, most common presenting complaint reported was breast lump (58.3%, n=112/192). The demographic and clinical characteristics are summarized in Table 1.

Prevalence of Anxiety and Depression

Used as a screening tool, the prevalence (95% CI) of those at risk for anxiety requiring further clinical evaluation was n = 46.4% (39.2%, 53.7%) and it was 29.7% (23.3%, 36.7%) for those at risk for major depression that warrants further clinical evaluation by a mental health provider. The details of severity are shown in Table 1.

Predictors of Anxiety

The predictors (aOR; 95% CI; *P* value) of anxiety were age (1.053; 1.024, 1.083; p<0.001) and post-menopausal status (2.475; 1.200, 5.103; p=0.014). The details of univariate and multivariable analysis of anxiety are given in Table – 3.

Predictors of Depression

The predictors (aOR; 95% CI; *P* value) of depression were age (0.954; 1.927, 0.981; p=0.001) and rural place of residence (2.362; 1.023, 5.433; p=0.044). The details of univariate and multivariable analysis of depression are given in Table – 4.

Discussion:

We conducted a cross sectional study among women seeking medical attention in the breast clinic at a tertiary care teaching hospital, in Mumbai city of India to estimate the prevalence of those at risk for generalized anxiety disorder and major depression requiring further clinical evaluation by a mental health professional. Among N = 192 patients, the prevalence (95% CI) of those at risk for anxiety was n = 46.4% (39.2%, 53.7%) and it was 29.7% (23.3%, 36.7%) for those at risk for major depression. Older women and those in the post-menopausal stage were observed to be at an elevated risk of developing anxiety. Whereas, young individuals and women residing in rural areas were found to have a higher likelihood of experiencing depression.

According to our results, 46.4% of the patients were at risk for anxiety and 29.7% were at risk for major depression. This is quite high when compared to the prevalence in the general population of India. As per the national mental health survey, the current weighted prevalence of anxiety disorders was 2.57% (95% CI: 2.54, 2.60). [17] Similarly, with regards to depression in the general population the weighted prevalence of lifetime and current depressive disorders in a study conducted across 12 Indian states in n = 34802 adults was 5.25% (95% CI: 5.21%, 5.29%) and 2.68% (95% CI: 2.65%, 2.71%), respectively. [18] It is not surprising that our participants were more likely to experience anxiety and depressive

symptoms not just out of fear of cancer but also out of fear of losing sexuality or fear of rejection, which is much more associated with breast diseases than diseases of other non-sexual body parts.

With regards to the predictors of anxiety, we found that for every one-year increase in age, there is approximately a 5% increased chance of being anxious. Similarly, post-menopausal women (as against pre-menopausal women) have approximately 2.5 times the increased odds of suffering from anxiety. This is probably because, awareness about malignant disorders is quite good these days among the general publica and the participants are likely to be aware that increasing age and post-menopausal status are an independent risk factor for malignant diseases.

On the contrary, we report that there is approximately a 5% decreased chance of depression with every one-year increase in age suggesting that younger women are more at risk for depression. This is most likely because associated with concerns regarding the marriage and family life. As per the 2005 Indian Human Development Survey, less than 5% of women had the "primary role in choosing their husbands". [19] This most compellingly indicates that why younger patients could have higher depression – fear of loss of cosmesis, decrease in "marriageability quotient", and of losing her identity. In a study on breast cancer patients, younger women were found to have higher depression scores, [20] explained by the fact that this age group women have higher aspirations than the elderly

On a similar note, rural women had approximately 2.4 times the increased odds of being at risk for depression as compared to their urban peers. This is in line with the general trends observed in developed countries in rural as against the urban population. [21] Many factors

could explain this difference and they are as follows: higher prevalence of lower socioeconomic population with lack of ample economic opportunities, limited education and lack of awareness, stigma associated with mental illnesses, lack of quality healthcare services, including mental health services, traditional gender roles and expectations such as household chores, childcare and caregiving for elderly family members leading to higher levels of stress and emotional exhaustion, and sometimes even social isolation with limited social interaction and support networks. [21] In India, although many studies suggest that there is higher prevalence of mental disorders among the urban public than the rural, we believe that under reporting due to various above-mentioned reasons could be a factor for the difference observed.

The strength of our study is that it has a sufficiently large sample size and does not differentiate based on the final diagnosis (benign or malignant). However, there are a few limitations as well. Since it was not a cohort study, the diagnosis whether benign or malignant was not known which could have further caused changes in mood. Also, the actual prevalence of anxiety and disorder could not be ascertained as their status of evaluation by a mental healthcare provider was unknown. We recommend cohort studies in the future to overcome these limitations. Further, the study is a single centre study from a large metropolis and hence the results may not be generalizable to the entire state or the country. More large multi-centre studies are required to further confirm the findings of our study.

In summary, the risk for generalized anxiety disorder and major depression requiring further clinical evaluation by a mental health professional is quite high among patients seeking breast care services when compared to the general population. Elderly women and post-menopausal

status were likely to be at increased risk for anxiety while young age and rural women were identified to be more at risk for depression. Thus, we recommend routine screening for mental health issues at a breast clinic and implementing quality of life (QOL) enhancing measures for better overall holistic outcomes, especially those who are at high risk. We believe this would go a long way in identifying and managing these otherwise neglected psychological illnesses.

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Conflicts of interest: None to Declare

Declarations:

- Funding statement - None received
- Ethics approval statement – Study was approved by Institutional Ethics Committee, Seth GS Medical College & KEM Hospital, Mumbai vide reference number EC/OA-181/2020, dated ____.
- Patient consent statement - Written informed consent obtained from all participants before enrolling into the study
- Permission to reproduce material from other sources - Not applicable

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Table 1: Demographic characteristics and presenting complaints.

Variable	Category	Frequency (N=192)	%
Age group (years)	18 to 44	126	65.6
	45 to 55	52	27.1
	≥56	14	7.3
Menopause Status	Pre-menopausal	145	75.5
	Post-menopausal	47	24.5
Residence	Rural	30	15.6
	Urban	162	84.4
Education	Illiterate	24	12.5
	School	107	55.7
	College	61	31.8
Occupation	Not employed	106	55.2
	Employed	86	44.8
Marital Status	Not married	38	19.8
	Married	154	80.2
Presenting Complaints	Lump	112	58.3
	Pain	27	14.1
	Nipple discharge	7	4.6
	>1 symptom	46	24.0

Table 2: Severity of Anxiety and Depression

Scale	Category		Frequency (N = 192)	Percentage (%)
	Score range	Interpretation		
Generalized Anxiety Disorder Scale - 7	0 – 5	No Anxiety	29	15.1
	6 – 10	Mild	93	48.4
	11 – 15	Moderate	66	34.4
	16 - 21	Severe	4	2.1
Patient Health Questionnaire - 9	0 – 4	No Depression	40	20.8
	5 – 9	Mild	85	49.5
	10 – 14	Moderate	52	27.1
	15 – 19	Moderately Severe	3	1.6
	20 - 27	Severe	2	1.0

Table 3: Predictors of Anxiety – Univariate and Multivariable analysis

Variable*	Univariate analysis		Multivariable analysis		
	Odds Ratio	*P* Value	Adjusted Odds ratio	95% Confidence Intervals	*P* value
Age	1.050	<0.001	1.053	1.024, 1.083	<0.001
Menopausal Status	1.807	0.081	2.475	1.200, 5.103	0.014
Residence	1.189	0.663	Not included in the analysis		
Education	1.578	0.143	0.723	0.444, 1.177	0.192
Occupation	0.767	0.362	Not included in the analysis		
Marital Status	1.562	0.221	Not included in the analysis		
Presenting Complaints	0.764	0.432	Not included in the analysis		

Nagelkerke R square = 0.138

* Age – taken as continuous variable. For other variables those categories coded as risk (code = 0) are as follows: Menopausal status: post-menopausal, residence: rural, education: illiterate, occupation: unemployed, marital status: unmarried, Presenting complaints: > than one

Table 4: Predictors of Depression – Univariate and Multivariable analysis

Variable*	Univariate analysis		Multivariable analysis		
	Odds Ratio	***P* Value**	**Adjusted Odds ratio**	**95% Confidence Intervals**	***P* value**
Age	0.956	0.001	0.954	0.927, 0.981	0.001
Menopausal Status	1.006	0.986	Not included in the analysis		
Residence	2.051	0.079	2.362	1.023, 5.453	0.044
Education	1.107	0.763	Not included in the analysis		
Occupation	0.706	0.271	Not included in the analysis		
Marital Status	1.300	0.496	Not included in the analysis		
Presenting Complaints	1.107	0.763	Not included in the analysis		

Nagelkerke R square = 0.106

* Age – taken as continuous variable. For other variables those categories coded as risk (code = 0) are as follows: Menopausal status: post-menopausal, residence: rural, education: illiterate, occupation: unemployed, marital status: unmarried, Presenting complaints: > than one

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5-6
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	6-7
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*7-8*
Bias	9	Describe any efforts to address potential sources of bias	8
Study size	10	Explain how the study size was arrived at	8-9
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	10
		(*b*) Describe any methods used to examine subgroups and interactions	NA
		(*c*) Explain how missing data were addressed	NA
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	NA
		(*e*) Describe any sensitivity analyses	NA
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	10
		(b) Give reasons for non-participation at each stage	10
		(c) Consider use of a flow diagram	NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	10
		(b) Indicate number of participants with missing data for each variable of interest	NA
Outcome data	15*	Report numbers of outcome events or summary measures	10
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	10-11

		(*b*) Report category boundaries when continuous variables were categorized	NA
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA
Discussion			
Key results	18	Summarise key results with reference to study objectives	11
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	12-13
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12-13
Generalisability	21	Discuss the generalisability (external validity) of the study results	13
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	14

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Screening for those at risk for anxiety and depression warranting further clinical evaluation among patients presenting to breast services: a single-centre, cross-sectional study

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Screening for those at risk for anxiety and depression warranting further clinical evaluation among patients presenting to breast services: a single-centre, cross-sectional study

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Abstract

Objectives: Studies show that anxiety and depression are widespread across patients presenting to outpatient services for medical illnesses. We expect similar or even higher prevalence in patients with breast complaints, owing to the relevance of breasts in terms of sexuality, identity, and confidence. Thus, this study was proposed to estimate the prevalence and identify risk factors for being at risk for anxiety and depression in patients seeking breast services.

Design: Descriptive cross-sectional study.

Setting: Tertiary care teaching hospital in Mumbai, Western India.

Participants: Patients seeking breast services for either benign or malignant conditions.

Outcome measures: Proportion of those at risk for clinical depression (defined as Patient Health Questionnaire 9 score ≥ 10), proportion of those at risk for clinical anxiety warranting further clinical evaluation (defined Generalised Anxiety Disorder 7 score ≥ 10) and their predictors.

Results: A total of 208 patients were screened, and 192 consenting patients were enrolled. The prevalence (95% CI) of those at risk for anxiety requiring further clinical evaluation was 46.4% (39.2%, 53.7%), and for those at risk for major depression that warrants further clinical evaluation by a mental health provider was 29.7% (23.3%, 36.7%). The predictors (aOR; 95% CI; *P* value) of anxiety were age (1.053; 1.024, 1.083; p<0.001) and post-menopausal status (2.475; 1.200, 5.103; p=0.014). The predictors (aOR; 95% CI; *P* value) of depression were age (0.954; 1.927, 0.981; p=0.001) and rural place of residence (2.362; 1.023, 5.433; p=0.044).

Conclusions

There is a high prevalence of being at risk for anxiety and depression among patients who seek breast services warranting further clinical evaluation. The predictors for being at risk for anxiety were higher age and post-menopausal status, and for those at risk for depression were young age and residing in rural areas.

Keywords: Breast surgery, Anxiety disorders, Depression & mood disorder, Patient Reported Outcome Measures.

Strengths and limitations of this study

- The study has a sufficient sample size and does not differentiate based on the final diagnosis (benign or malignant).
- The diagnosis, whether benign or malignant, was unknown, which could have further caused mood changes.
- The actual prevalence of anxiety and depression could not be ascertained pending clinical evaluation; only “at risk” individuals were identified.
- As this was a single-centre study, the results may not be generalizable to the state or country.

INTRODUCTION

Depression, anxiety, and substance abuse are the most common yet often missed psychiatric illnesses in non-psychiatric outpatients [1,2], and the lifetime prevalence of depression and generalized anxiety disorder (GAD) is 12.1% and 3.7%, respectively. [3,4] As psychological factors are increasingly recognized as determinants of therapeutic progress, the psychosocial and cultural needs of patients ought to be considered more so because the quality of life (QOL) is an independent predictor of disease-related outcomes. [5] However, the first step towards targeting mental well-being as a part of comprehensive care is to identify the problem via patient screening and determine the presence of anxiety and/or depression, which are missed out on routine clinical assessment.

Breast-related symptoms are expected to elicit anxiety and/or depression, owing to the various fears generated in a woman – of cancer, losing a vital sexual organ, rejection by family, or social outcasting, in addition to expenses, hospitalization, and surgery. For instance, Srivastava et al. from North India reported that among women with benign breast diseases, 27% had major depression, 58% had minor depression and 27% had anxiety. [6] Similarly, a meta-analysis of 36 studies that included 16,298 breast cancer patients between 2000 and 2018 estimated the prevalence of anxiety to be at 41.9% [95% confidence interval (CI): 30.7, 53.2] [7] The prevalence of depression was said to be 10–25% of patients diagnosed with breast cancer. [8] Thus, it becomes essential to understand the burden of anxiety and/or depression in this group of patients. A thorough literature search in the English language found that only very few studies had been conducted to estimate the prevalence of psychiatric illnesses in breast outpatients, inclusive of patients with benign breast conditions,

as most studies were conducted among breast cancer patients, and the data from India was also limited.

Hence, the objective of this study was to determine the prevalence and predictors of being at risk for anxiety and depression in patients presenting to the breast services of a tertiary care centre in Western India using standard validated scales such as the Generalized Anxiety Disorder Scale-7 (GAD-7) for anxiety and Patient Health Questionnaire-9 (PHQ 9) for depression.

METHODS

Ethics

The research received authorization from the Institutional Ethics Committee at the hospital where it took place, identified by reference number EC/OA-181/2020, dated 19.02.2021. Before joining the study, all potential participants provided written informed consent. The research adhered to the principles of Good Clinical Practice outlined in the Declaration of Helsinki (World Medical Association, Fortaleza, 2013) and followed the National Guidelines for Ethical Research in Human Participants (Indian Council of Medical Research Guidelines, 2017)

Study design and setting

A descriptive, cross-sectional study was conducted between 20th February 2021 and 15th June 2021 in a public tertiary care teaching hospital in Mumbai, a metropolitan city in Western India. The civic body– Brihanmumbai Municipal Corporation runs the hospital and it caters predominantly to low- and middle-income people at a highly subsidized cost. The hospital runs a separate breast-services clinic comprised mainly of surgeons, social health worker, and

pain and palliative care physicians.

Study sample

All female patients 18 years and above with no history of dementia or lack of insight who attended the breast services for any breast-related complaints were included in the study. Those who did not provide written informed consent were excluded from the study.

Variables

The dependent variables of interest were the GAD-7 and PHQ-9 scores. The predictor (independent) variables of interest were age, menopause status, place of residence, education, occupation, marital status, and presenting complaints (Single breast-related symptom *vs* more than one)

Study procedures

After obtaining written informed consent, data were collected by face-to-face interviews using freely accessible universal questionnaires namely GAD-7 and PHQ-9. In addition, the following demographic characteristics, namely age, menopausal status, place of residence, marital status, education level, and occupational status, were recorded in a case record form. The clinical data, including presenting symptoms, were also recorded. Those who were identified as at risk for anxiety and major depression requiring further evaluation by a mental health professional were referred to a certified counselor who was available as a part of the breast services team.

Data sources and measurements

Demographics and clinical characteristics were elicited based on patient history. Anxiety was evaluated using the GAD-7 scale. It is a 7-item, self-rated scale developed as a screening tool

and severity indicator for generalized anxiety disorder. [9] Scores range from 0 to 21, with higher scores indicating more severe GAD symptoms. While screening, a cut-off score of 10 was identified as the optimal point for risk of anxiety, warranting further clinical evaluation. It has a high sensitivity (89%) and specificity (82%) as screening at this cut-off point. At follow-up, scores of 5, 10, and 15 are interpreted as representing mild, moderate, and severe levels of anxiety. [10]

Depression was evaluated using the PHQ-9, which is a self-administered depression module. [11] It is a nine-item scale representing the DSM-IV criteria for major depression, with each symptom criteria being scored as a Likert from 0 (not at all) to 3 (nearly every day) [12]. A PHQ-9 score ≥10 had a sensitivity of 88% and a specificity of 88% for major depression that warrants further clinical evaluation by a mental health provider. PHQ-9 scores of 5, 10, 15, and 20 represent mild, moderate, moderately severe, and severe depression, respectively. [12] The validated translations of both GAD-7 and PHQ-9 questionnaires in local languages *viz* Hindi and Marathi that are freely available online were used in this study.

Bias

Response biases such as social desirability (SDR) and acquiescent (ACQ) responding are well known in the setting of self-reported psychometric scales that use the Likert scale. [13] SDR stands for the inclination to react in a way that aligns with what is considered favorable by salient others. At the same time, ACQ signifies the inclination to favor the positive end of the rating scale, regardless of the item's content. [13] An attempt to mitigate the bias was made by anonymizing data collection and permitting self-administration of the questionnaires in the language of their understanding if the participant was literate. Similarly, referral bias

due to referral of a particular group of patients based on the variables of interest [14] was negligible as the study was conducted in the general surgery department where all patients requiring breast services, irrespective of their psychological state, took treatment.

Sample size estimation and sampling technique

Assuming the prevalence of depression and/or anxiety in patients seeking breast services at a similar rate as seen in the general Indian medical outpatients, an estimated prevalence (p) of 39.3% was considered. [15] The sample size estimated using the Cochran's formula $[Z_\alpha^2 p(100-p)/d^2]$, [16] assuming a relative precision (d) = 20%, alpha error = 5% (corresponding Z score = 1.96 ≈ 2), power of the study to be 80%, was n = 154. We decided to increase the same by 30% to N = 192, accounting for non-responders and cognitive and response bias due to the sensitive nature of the study measures.

A systematic random sampling technique was followed where every nth patient who attended the breast services were approached for consent, n being chosen randomly for each day between two and five using lots.

Data management

Information was initially gathered using a pen and paper format on a case record form, which was subsequently converted into digital format using Microsoft Excel (Publisher: Microsoft Corporation, Redmond, Washington, USA, 2016). Stringent measures were taken to ensure the confidentiality of patient data. Participant files were securely stored in locked cupboards, and digital data was safeguarded on password-protected computers. The analysis was conducted solely on data that had been deidentified and coded reversibly. Statistical analysis was performed using Statistical Product and Service Solutions (SPSS) for Windows, Version

25.0 (Publisher: IBM Corp., Armonk, New York, USA, 2017).

Statistical analyses

Demographic and clinical characteristics were presented as mean with standard deviation (SD) for age and frequencies and percentages for the rest of the data. A score of ≥ 10 in GAD-7 or PHQ-9 at screening was considered as those at risk for anxiety and major depression warranting further clinical evaluation. The prevalence was represented as proportions with 95% CI. Univariate and Multivariable analysis to identify the predictors of anxiety and depression was conducted using binary logistic regression. All hypothesized predictors whose p-value < 0.2 in the univariate analyses alone were included in the multivariable analysis. The level of significance for all analyses was set at $p < 0.05$.

Patient and public involvement

None.

RESULTS

Demographic and clinical characteristics

A total of n = 208 patients were screened, and N = 192 provided consent. The rest (n = 16) did not consent to participate in the study. The mean (SD) age of our study participants was 38.7 (11.8) years, and most of them were from the age group of 18-44 years (64.6%, n = 126/192). A total of 75.5% (n = 145/192) patients were pre-menopausal, and 84.4% (n = 162/192) were residing in urban areas. Clinically, the most common presenting complaint reported was breast lump (58.3%, n=112/192). The demographic and clinical characteristics are summarized in Table 1.

Prevalence of being at risk for anxiety and depression

Used as a screening tool, the prevalence (95% CI) of those at risk for anxiety requiring further clinical evaluation was n = 46.4% (39.2%, 53.7%), and it was 29.7% (23.3%, 36.7%) for those at risk for major depression that warrants further clinical evaluation by a mental health provider. The details of severity are shown in Table 2.

Predictors of being at risk for anxiety

The predictors (aOR; 95% CI; *P* value) of anxiety were age (1.053; 1.024, 1.083; p<0.001) and post-menopausal status (2.475; 1.200, 5.103; p=0.014). The details of univariate and multivariable analysis of anxiety are given in Table 3.

Predictors of being at risk for depression

The predictors (aOR; 95% CI; *P* value) of depression were age (0.954; 1.927, 0.981; p=0.001) and rural place of residence (2.362; 1.023, 5.433; p=0.044). The details of univariate and multivariable analysis of depression are given in Table 4.

DISCUSSION

We conducted a cross-sectional study among women seeking medical attention in the breast clinic at a tertiary care teaching hospital in Mumbai city of India to estimate the prevalence of those at risk for generalized anxiety disorder and major depression requiring further clinical evaluation by a mental health professional. Among N = 192 patients, the prevalence of those at risk for anxiety and depression was 46.4% and 29.7%, respectively. Older women and those in the post-menopausal stage were observed to be at an elevated risk of developing anxiety. At the same time, young individuals and women residing in rural areas were found to have a higher likelihood of experiencing depression.

The prevalence of those at risk for anxiety and depression is relatively high compared to the

prevalence in the general population of India. As per the national mental health survey, the current weighted prevalence of anxiety disorders was 2.57% (95% CI: 2.54, 2.60). [17] Similarly, with regards to depression in the general population, the weighted prevalence of lifetime and current depressive disorders in a study conducted across 12 Indian states in n = 34802 adults was 5.25% (95% CI: 5.21%, 5.29%) and 2.68% (95% CI: 2.65%, 2.71%), respectively. [18] It is not surprising that our participants were more likely to experience anxiety and depressive symptoms not just out of fear of cancer but also out of fear of losing sexuality or fear of rejection, which is much more associated with breast diseases than diseases of other non-sexual body parts.

With regards to the predictors of anxiety, we found that for every one-year increase in age, there is approximately a 5% increased chance of being anxious. Similarly, post-menopausal women (as against pre-menopausal women) have approximately 2.5 times the increased odds of suffering from anxiety. This is probably because awareness about malignant disorders is quite good these days among the general public, and the participants are likely to be aware that increasing age and post-menopausal status are independent risk factors for malignant diseases.

On the contrary, we report that there is approximately a 5% decreased chance of depression with every one-year increase in age, suggesting that younger women are more at risk for depression. This is most likely associated with concerns regarding marriage and family life. As per the 2005 Indian Human Development Survey, less than 5% of women had the "primary role in choosing their husbands." [19] This most compellingly indicates why younger patients could have higher depression – fear of loss of cosmesis, decrease in

"marriageability quotient," and of losing her identity. In a study on breast cancer patients, younger women were found to have higher depression scores, [20] explained by the fact that this age group of women has higher aspirations than the elderly

On a similar note, rural women had approximately 2.4 times the increased odds of being at risk for depression as compared to their urban peers. This is in line with the general trends observed in developed countries in rural as against the urban population. [21] Many factors such as higher prevalence of lower socioeconomic population with lack of ample economic opportunities, limited education and lack of awareness, stigma associated with mental illnesses, lack of quality healthcare services, including mental health services, traditional gender roles and expectations such as household chores, childcare and caregiving for elderly family members could explain the urban-rural disparity. These factors also lead to higher levels of stress and emotional exhaustion, and sometimes even social isolation with limited social interaction and support networks. [21, 22] In India, although many studies suggest that there is a higher prevalence of mental disorders among the urban public than the rural, we believe that underreporting due to various reasons mentioned above could be a factor for the difference observed. [21]

The strength of our study is that it has a sufficiently large sample size and does not differentiate based on the final diagnosis (benign or malignant). However, there are a few limitations as well. Since it was not a cohort study, the diagnosis, whether benign or malignant, was not known, which could have further caused mood changes; also, the actual prevalence of anxiety and disorder could not be ascertained as their status of evaluation by a mental healthcare provider was unknown. Also, since there was no longitudinal follow-up

done and the largest proportion reported to have mild- moderate anxiety and/or depression, the stability of the diagnosis over a period of time, and its association with the illness, could not be ascertained. We recommend cohort studies in the future to overcome these limitations and plan for future interventional studies to evaluate survival rates, quality of life (QoL) and other outcomes. Further, the study is a single-centre study from a large metropolis; hence, the results may not be generalizable to the entire state or country. More large multicentre studies are required to confirm our study's findings further.

In summary, the risk for generalized anxiety disorder and major depression requiring further clinical evaluation by a mental health professional is relatively high among patients seeking breast care services when compared to the general population. Thus, clinicians and health care professions must include mental health consultations in the treatment plan. Alternatively, a multidisciplinary team consisting of mental health professionals may be formed to provide holistic breast-care services. Older women and post-menopausal status were likely to be at increased risk for anxiety, while young age and rural women were identified to be more at risk for depression. Thus, we recommend routine screening for mental health issues at a breast clinic and implementing QoL enhancing measures for better overall outcomes, especially for those who are at high risk. We believe this would go a long way in identifying and managing these otherwise neglected psychological illnesses.

Competing interests

None to declare.

Funding

None.

Ethics approval and consent to participate

The study was approved by the Institutional Ethics Committee, Seth GS Medical College & KEM Hospital, Mumbai, vide reference number EC/OA-181/2020 (19.02.2021). Written informed consent was obtained from all participants before enrolling in the study

Contributors

SH: concept and design, data interpretation, drafting the manuscript. SR, SS: concept and design, data interpretation, critical review of manuscript. KVAJ, BK: data collection, critical review of manuscript. JPR: design, statistical analysis and data interpretation, drafting the manuscript. All authors have approved the final version of the manuscript to be published and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Data availability statement

Deidentified individual participant data are available from the corresponding author and will be shared upon reasonable request for future research/ policy or guideline development.

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Table 1. Demographic characteristics and presenting complaints

Variable	Category	Frequency (N=192)	%
Age group (years)	18 to 44	126	65.6
	45 to 55	52	27.1
	≥56	14	7.3
Menopause Status	Pre-menopausal	145	75.5
	Post-menopausal	47	24.5
Residence	Rural	30	15.6
	Urban	162	84.4
Education	Illiterate	24	12.5
	School	107	55.7
	College	61	31.8
Occupation	Not employed	106	55.2
	Employed	86	44.8
Marital Status	Not married	38	19.8
	Married	154	80.2
Presenting Complaints	Lump	112	58.3
	Pain	27	14.1
	Nipple discharge	7	4.6
	>1 symptom	46	24.0

Table 2. Severity of anxiety and depression

Scale	Category		Frequency (N = 192)	Percentage (%)
	Score range	Interpretation		
Generalized Anxiety Disorder Scale - 7	0 – 4	No Anxiety	17	8.9
	5 – 9	Mild	86	44.8
	10 – 14	Moderate	77	40.1
	15 - 21	Severe	12	6.3
Patient Health Questionnaire - 9	0 – 4	No Depression	40	20.8
	5 – 9	Mild	85	49.5
	10 – 14	Moderate	52	27.1
	15 – 19	Moderately Severe	3	1.6
	20 - 27	Severe	2	1.0

Table 3. Predictors of anxiety—univariate and multivariable analysis

Variable*	Univariate analysis		Multivariable analysis		
	Odds Ratio	*P* Value	Adjusted Odds ratio	95% Confidence Intervals	*P* value
Age	1.050	<0.001	1.053	1.024, 1.083	<0.001
Menopausal Status	1.807	0.081	2.475	1.200, 5.103	0.014
Residence	1.189	0.663	Not included in the analysis		
Education	1.578	0.143	0.723	0.444, 1.177	0.192
Occupation	0.767	0.362	Not included in the analysis		
Marital Status	1.562	0.221	Not included in the analysis		
Presenting Complaints	0.764	0.432	Not included in the analysis		

Nagelkerke R square = 0.138.

* Age – taken as a continuous variable. For other variables, those categories coded as risk (code = 0) are as follows: Menopausal status: post-menopausal, residence: rural, education: illiterate, occupation: unemployed, marital status: unmarried, Presenting complaints: > than one.

Table 4. Predictors of depression—univariate and multivariable analysis

Variable*	Univariate analysis		Multivariable analysis		
	Odds Ratio	*P* Value	Adjusted Odds ratio	95% Confidence Intervals	*P* value
Age	0.956	0.001	0.954	0.927, 0.981	0.001
Menopausal Status	1.006	0.986	Not included in the analysis		
Residence	2.051	0.079	2.362	1.023, 5.453	0.044
Education	1.107	0.763	Not included in the analysis		
Occupation	0.706	0.271	Not included in the analysis		
Marital Status	1.300	0.496	Not included in the analysis		
Presenting Complaints	1.107	0.763	Not included in the analysis.		

Nagelkerke R square = 0.106.

* Age – taken as a continuous variable. For other variables, those categories coded as risk (code = 0) are as follows: Menopausal status: post-menopausal, residence: rural, education: illiterate, occupation: unemployed, marital status: unmarried, Presenting complaints: > than one.

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5-6
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	6-7
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*7-8*
Bias	9	Describe any efforts to address potential sources of bias	8
Study size	10	Explain how the study size was arrived at	8-9
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	10
		(*b*) Describe any methods used to examine subgroups and interactions	NA
		(*c*) Explain how missing data were addressed	NA
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	NA
		(*e*) Describe any sensitivity analyses	NA
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	10
		(b) Give reasons for non-participation at each stage	10
		(c) Consider use of a flow diagram	NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	10
		(b) Indicate number of participants with missing data for each variable of interest	NA
Outcome data	15*	Report numbers of outcome events or summary measures	10
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	10-11

		(*b*) Report category boundaries when continuous variables were categorized	NA
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA
Discussion			
Key results	18	Summarise key results with reference to study objectives	11
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	12-13
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12-13
Generalisability	21	Discuss the generalisability (external validity) of the study results	13
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	14

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.