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Research Article

Perceived Distress in Women with Breast Cancer during COVID-19 Outbreak: A **Multicenter Italian Study**

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Abstract

Breast Cancer (BC) patients during the COVID-19 outbreak could have an increased risk of developing anxiety and depression. This study aimed to assess the emotional distress of women with BC during the COVID-19 pandemic. Women with a diagnosis of primary BC, at any stage of diagnosis and treatment (i.e., at the moment of diagnosis or receiving active treatment or in follow-up), were prospectively enrolled between April 1- May 1, 2020. The Perceived Stress Scale (PSS) was used to measure the global perceived stress by BC patients. Data from 154 women with a diagnosis of BC were prospectively collected and retrospectively analyzed. Of them, 57 patients underwent neoadjuvant or adjuvant therapy (Group A), 26 patients awaiting surgery or to start chemo/radiation therapy (Group B), whereas 71 were in follow-up (Group C). Overall, the mean PSS' score was 19 ± 7.4 (range 3 to 35). This showed a high level of perceived stress among the entire population. In particular, a higher score was registered for patients of group A, with a PSS score of 19.5 ± 7.3. The health restriction secondary to the COVID-19 outbreak leads to an increase in distress in BC patients, as confirmed also by the level of PSS score.

Introduction

The Italian guidelines for the follow-up and assessment of oncological patients during the outbreak of the SARS-CoV-2 virus state that, in addition to the recommendations for the general population, outpatient visits and assessments (e.g., CT scans, endoscopies and blood tests) for patients not undergoing therapy can be postponed in consultation with their oncologist [1]. Furthermore, the guidelines state that personalized pathways should be established for patients undergoing surgery or chemotherapy to protect them from the risk of infection [1].

However, according to a recent UK study, during the

pandemic, the majority of patients with cancer or suspected cancer did not access healthcare services, with major declines in chemotherapy attendance (an average reduction of 66%) and urgent referrals for early diagnosis (an average reduction of 76%) [2].

The immunosuppressant effects of cancer and its treatment, in addition to pre-existing health conditions which often occur in cancer patients, make them a vulnerable group with an increased risk of complications from the virus. Delays in diagnosis, changes in standards of care, and fear of an increased risk of infection have had a significant psychological impact on these patients. They experience an emotional state of confusion caused by the need to undergo life-saving

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treatments and the fear of exposing themselves to the risk of contagion [3].

Particular attention must be given to patients with Breast Cancer (BC). Diagnosis and active treatment for BC cause significant emotional distress in these patients. Furthermore, long-term sequelae such as sleep disturbance, sexual dysfunction, and the potential onset of early menopause, as well as loss of fertility, could seriously affect quality of life and have serious psychological consequences for women with BC [4–6]. Then, if the general population commonly manifests confusion, anger, and post-traumatic stress disorder as a consequence of this pandemic condition [7], at the same time, BC patients could be at an increased risk of developing anxiety, depression, and Post-Traumatic Stress Disorder (PTSD) due to their psychological state [8–10].

Despite the growing body of literature on the clinical consequences of a SARS-CoV-2 infection, little is still known about its psychological implications for patients with BC. A recent study from England investigated the effect of disruption to scheduled oncology services on the emotional and cognitive vulnerability of patients affected by BC. The authors showed that concerns about the virus lead to an increased risk of developing affective disorders such as anxiety and depression. Furthermore, they found a direct correlation between the phase of the disease (diagnosis, treatment, or follow-up) and mental status [11–13].

Several questionnaires have been developed to measure perceived stress in cancer patients. Examples include the Questionnaire on Stress in Cancer Patients [14] and the Newly Diagnosed Breast Cancer Stress Scale [15,16]. The former assesses cancer-specific stressful situations, while the latter measures stress perceptions at the beginning of the breast cancer journey. Another well-known instrument for measuring perceived distress is the Perceived Stress Scale [17]. This 14-item self-report questionnaire investigates the extent to which daily life situations were perceived as unpredictable, uncontrollable, and stressful over the previous month. A shortened 10-item version [17,18] has also been developed and used in both cancer and non-cancer clinical scenarios. Recently, a study investigated the usefulness of the PSS-10 in evaluating 215 Spanish women with breast cancer. The authors found that the PSS-10 is an adequate tool for measuring perceived stress in the context of breast cancer and that it can be used to identify women who need psychological intervention [19].

Accordingly, using the Perceived Stress Scale (PSS-10), we assessed in three different Italian Breast Cancer Centers (BCC) the emotional distress of women with BC during the COVID-19 pandemic.

Method

Women diagnosed with primary Breast Cancer (BC) at any stage (i.e. at the time of diagnosis, during active treatment, or follow-up/post-treatment) were prospectively enrolled in the study at three Italian breast cancer centres (the Oncology Department at Misericordia Hospital in Grosseto, the Breast

Unit at Santo Spirito Hospital, and San Filippo Neri Hospital -Asl Roma 1 in Italy) between 1 April and 1 May 2020. The study was performed in accordance with the Declaration of Helsinki. The research received approval from our Institutional Review Board (reference number 17607, approved by the 'Comitato Etico di Area Vasta Sudest - C.E.A.V.S.E'). All patients signed an informed consent form. Between 1 April and 1 May 2020, participants were asked to complete the Perceived Stress Scale (PSS), which was sent via email after a telephone interview. A database was established and maintained prospectively to collect demographic data (patient ID, age, and cancer stage), treatment status, and PSS score. According to their treatment phase, patients were divided into three groups: group A comprised patients undergoing neoadjuvant/adjuvant therapy; group B comprised patients awaiting surgery or the commencement of chemotherapy or radiotherapy (both neoand adjuvant therapies); Group C comprised patients who had undergone a minimum of six months of follow-up after surgery or adjuvant chemotherapy. We included this population to assess the perceived stress of patients, for whom each control became a source of stress due to the fear of disease recurrence. Indeed, the normal scheduled follow-up for these patients could be delayed compared to previous years due to the period of the pandemic.

The Perceived Stress Scale – 10, described by Cohen S, et al. [17,18], is a 10-item questionnaire used to measure the global perceived stress, as thoughts and feelings experienced, in the past month. It is a robust predictor of health and disease, simple to do, and easy to understand. There are questions as "How often did you feel unable to deal with everything that needed to be done?" and "How often did you feel nervous and stressed?". Each of these questions has a 5-point response scale: never [0], rarely [1], once in a while [2], often [3], very often [4]. For the questions 4-5-7-8, the score is inverted never [4], rarely [3], once in a while [2], often [1], very often [0]. Total scores range from 0 to 40, where a higher score corresponds to a higher level of perceived stress. Total PSS score is classified as: 0-10 low perceived stress, 11-14 medium perceived stress, 15-18 medium-high perceived stress, and > 19 high perceived stress.

Statistical analysis

Statistical analysis was performed using SPSS 18.0 statistical software (SPSS, Chicago, IL, USA). Continuous data are presented as mean ± standard deviation, whereas categorical data are expressed as absolute numbers and percentages. *p* -*values* are obtained with a T-test for a continuous variable.

Results

Data from 154 women with a diagnosis of BC were prospectively collected and retrospectively analyzed. The mean age was 56.6 ± 11.3 years (range 29 - 86 years). Of them, 57 patients (37%) underwent neo adjuvant or adjuvant therapy (Group A), 26 patients (17%) were awaiting surgery or to start chemo/radiation therapy (Group B), whereas 71 (46%) were in follow—up (Group C - Off-Therapy patients). Three of them had a metastatic disease (Table 1).

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Overall, during the pandemic, the mean PSS score in BC patients was 19 \pm 7.4 (range 3 to 35). This indicated a high level of perceived stress among the entire population. In particular, the highest score was registered for patients of group A, with a PSS score of 19.5 \pm 7.3. Patients in group B, awaiting to start chemo/radiotherapy or surgery, had a PSS score of 19.4 \pm 7.3. Finally, patients of group C had a PSS score of 19 \pm 7.5. Comparing the PSS score value between the 3 groups, there was no statistically significant difference (Table 2).

The analysis of the level of stress among the three groups showed that 58% of patients of group C had a higher level of stress (PSS score > 19), compared with the 49 % and 47% of patients of groups A and B, respectively (Table 3).

Discussion

The results of our study showed that breast cancer patients experienced high levels of stress as a consequence of the healthcare restrictions imposed by the pandemic, with a mean PSS score of 19 ± 7.4 (range 3-35).

To date, there have been few studies investigating stress levels among oncology patients during the pandemic. Furthermore, the available studies principally focus on the Chinese population. A survey investigating the psychological impact and mental health status of the Chinese population was performed during the outbreak of the virus. The authors used

Table 1: Demographic outcomes.

	154 patients with a diagnosis of BC	
Age, mean ± SD	56.6 ± 11.3 years	
Group A n /%	57/37	
Group B n /%	26/17	
Group C n /%	71/46	
Patients with metastatic disease n /%	3/	

Group A: Patients undergoing neoadjuvant or adjuvant therapy.

Group B: Patients awaiting surgery or the start of chemotherapy/radiotherapy.

Group C: Patients in follow-up: off-therapy patients.

Table 2: PSS score according to the Groups. All values are expressed as medians and Standard Deviation (SD). p - values are obtained with a T-test for a continuous variable.

	Groups A	Groups B	p - value
PSS' score value Mean ± SD	19.5 ± 7.3	19.4 ± 7.3	0,935
	Groups A	Groups C	p - value
PSS' score value Mean ± SD	19.5 ± 7.3	19 ± 7.5	0,167
	Groups B	Groups C	p - value
PSS' score value Mean ± SD	19.4 ± 7.3	19 ± 7.5	0.345

Table 3: Level of Stress between the groups.

Stress Level	Groups A (n = 57)	Groups B (<i>n</i> = 26)	Groups C (n = 71)
Low stress, n (%)	8 (14)	7 (27)	8 (11)
Medium stress, n (%)	11 (19)	3 (11)	10 (14)
Medium High, n (%)	10 (18)	4 (15)	12 (17)
High, n (%)	28 (49)	12 (47)	41 (58)

the Impact of Event Scale-Revised (IES-R) and the Depression, Anxiety and Stress Scale (DASS-21). 53.8% of respondents rated the psychological impact of the pandemic as moderate or severe. The findings showed that female gender was significantly associated with higher levels of stress, anxiety, and depression, as well as a greater psychological impact resulting from the outbreak [7].

A large-scale nationwide survey of the general population of China was carried out to analyse psychological distress during the outbreak. The authors used the Peritraumatic Distress Index (PDI) to investigate the frequency of anxiety, depression, specific phobias, cognitive changes, avoidance and compulsive behaviours, physical symptoms, and loss of social functioning over the past week. CPDI scores range from 0 to 100: scores between 28 and 51 indicate mild to moderate distress, while scores >52 indicate severe distress. Of the 52,730 valid responses received (64.73% of which were from females), the authors found a mean CPDI score of 23.65 (±15.45). Multinomial logistic regression analysis revealed that the female group experienced significantly higher psychological distress than the male group [20].

A Chinese study was recently published comparing the psychological status of 207 patients with Breast Cancer (BC) and 684 female nurses during the outbreak of the novel coronavirus (SARS-CoV-2). The female nurses were divided into frontline nurses (those working in the emergency department, fever clinics, or the medical unit for patients with confirmed or suspected cases of COVID-19) and non-frontline nurses. The investigators used Chinese versions of the 9-item Patient Health Questionnaire (PHQ-9), the 7-item Generalised Anxiety Disorder Scale (GAD-7), the 7-item Insomnia Severity Index (ISI), and the 22-item Impact of Event Scale-Revised (IES-R) to evaluate Post-Traumatic Stress Disorder (PTSD). BC patients and frontline female nurses had comparable outcomes in terms of symptomatic anxiety, depression, sleep disorders, and PTSD, which were higher than those of non-frontline female nurses. Nevertheless, BC patients scored significantly higher than frontline nurses on the ISI [21].

A recently published UK study analysed the psychological impact of the outbreak of the SARS-CoV-2 virus on the cognitive and emotional health of a group of women affected by primary breast cancer (BC) who had their scheduled oncology services disrupted (i.e., had their appointments cancelled or delivered over the phone instead of in person). The authors used several tests, including the Functional Assessment of Cancer Therapy-Cognitive Scale (FACT-Cog, Version 3), the Rumination Response Scale (RRS), the self-report Hospital Anxiety and Depression Scale (HADS), and the Penn State Worry Questionnaire (PSWQ). The study showed that those who experienced disruptions to their oncology services had higher levels of general anxiety, depression, and emotional vulnerability related to the pandemic [11].

As in the above-mentioned study, women with BC in our study also experienced a high level of stress as a consequence of the outbreak of the virus on the healthcare system. In all groups, the majority of patients had a high PSS score: 49% in group A, 47% in group B, and 58% in group C.

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The higher level of stress in group C, compared to the other groups, could be explained by BC patients' enhanced fear of recurrence as a consequence of delayed follow-up. BC patients are afraid of dying; these treatments are 'lifesaving' and cannot be postponed. Furthermore, the dependence that these patients could develop on treatment plans must not be underestimated. As reported by Swainston, et al. disruption to the standard of care due to the outbreak of the novel Coronavirus (SARS-CoV-2) could have exacerbated anxiety, depression, and distress in BC patients. Delayed treatment (surgery or chemotherapy/radiotherapy), and the associated fear of an increased risk of disease recurrence and infection, are common among these patients. This could have worsened their usual sense of loneliness and powerlessness in the face of this condition. The result is an emotional state of confusion caused by the need to undergo life-saving treatments and the fear of exposing themselves or healthcare workers (e.g. physicians and nurses) to the risk of contagion [3].

Clinical implications

The results of our study confirm that the PSS-10 scale is a valid and reliable test for assessing distress in women with breast cancer, as demonstrated by a recent study by Soria-Reyes LM, et al. [19].

In this post-pandemic period, our study highlights the importance of screening for perceived distress in breast cancer patients at different stages of the disease, from diagnosis to follow-up after treatment. The PSS-10 could be useful in identifying patients who require psychological support during challenging life phases, such as after a breast cancer diagnosis.

Study limitations

The limitations of this study were its retrospective nature and the absence of a comparative group. Ideally, our results would be supported by prospective, multi-institutional studies with a larger sample size, comparing other types of oncological patients to investigate whether the PSS score increases equally as a consequence of a SARS-CoV-2 outbreak.

Conclusion

The results of our study showed that health restrictions secondary to the outbreak of the novel Coronavirus (SARS-CoV-2) lead to increased distress in BC patients. During this pandemic, these patients presented a high level of stress, with a mean PSS score of 19 \pm 7.4 (ranging from 3 to 35). Psychological interventions using video calls, for example, for oncology patients, should also be encouraged in the post-pandemic period to enhance compliance with lifesaving treatment and provide reassurance and ongoing psychological support.

Ethical compliance section

Compliance with ethical standards: All procedures performed in studies involving human participants were by the ethical standards of the [reference number 17607, approved by the "Comitato Etico di Area Vasta Sudest — C.E.A.V.S.E.] and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent: Informed consent was obtained from all patients included in the study.

Author contributions: Study conception and design: FC and GG. Acquisition of data: FC, MD, EC, DM, FC and PP. Analysis and interpretation of data: FC and GG. Drafting of manuscript: FC and GG. Critical revision of manuscript: MD, NF and CB.

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