

ORIGINAL ARTICLE

Psychological well-being in cancer outpatients during COVID-19

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Summary

Purpose: The psychological status of cancer outpatients receiving anti-neoplastic treatment during the lockdown in a Italian non-COVID Cancer Center, was been investigated with the following aims: to measure the levels of post-traumatic stress symptoms, depression and anxiety; to compare patients with different cancer sites; to compare the anxiety and depression levels measured in this emergency period between cancer and non-cancer patients and between cancer patients before and after the emergency.

Methods: The following questionnaires were used: The Hospital Anxiety and Depression Scale (HADS) and the Impact of Event Scale-Revised (IES-R). Worries regarding the COVID-19 on patients' lives, socio-demographic and clinical details were collected using a brief structured questionnaire.

Results: One-hundred seventy-eight outpatients were enrolled. We found that 55% of patients were above the cut-off

for HADS general scale and 23.7% had severe level of PTSD. The 68% of patients declared that their worries have increased during the pandemic especially for women. Patients with lung cancer have higher general distress compared with patients with breast cancer and lymphoma. The non cancer sample had values significantly higher both for the IES-R scales and for HADS Depression subscale. Finally, cancer patients who experienced the health emergency showed higher levels of anxiety than those measured 2 years ago.

Conclusion: Cancer out-patients of the present sample have severe post-traumatic stress symptoms and psychological distress, those with lung cancer are at higher risk and may need special attention. Non-oncological subjects have higher depression levels than cancer patients.

Key words: anxiety, depression, oncology, psycho-oncology, trauma and stressor related disorders, COVID-19

Introduction

Severe acute respiratory syndrome Coronavirus 2 (Sars-Cov 2) was first diagnosed in the Chinese city of Wuhan in October 2019 [1]. It quickly spread around the world, triggering a pandemic. Italy was one of the most affected countries, especially in the initial stages of the outbreak. On 30 April 2020, the total infections in Italy were 205,463 and 27,967 people died. The most affected regions were located

in Northern Italy, but the virus spread also to the rest of the peninsula, although to a lesser extent. In consideration of this serious health situation, the Italian government issued a decree that imposed a lockdown on the entire Italian population, in order to contain and control further diffusion of the COVID-19 virus and to protect both frail and elderly people.

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Among the restrictive and containment measures put in place, quarantine seems to have had the most significant and long-term negative psychological effects on the population, due to the ban on moving from one's own home and to forced isolation. Stress factors included increased quarantine duration, fears of infection, frustration, boredom, inadequate supplies, inadequate information, financial losses and stigma [2].

Typical symptoms of Post Traumatic Stress Disorder (PTSD) have been found, in particular depression, insomnia, perceived stress and adaptation disorder, with a prevalence in the female population. These results emerged from an Italian study conducted on 18.147 people interviewed during the peak of the pandemic, which also highlighted a constant association between young age and female gender with an increased risk of developing major mental disorders [3,4]. The Sars-CoV-2 pandemic has had a huge impact on cancer patients, both due to the reduction of hospital activities, and the association to the idea of greater mortality [5]. Furthermore, many characteristic symptoms of COVID19 such as fever, fatigue, dry cough, anorexia, myalgia and dyspnoea are the same as those routinely reported by cancer patients, both for the disease itself and for anticancer treatments. This carries the risk of confusion in ascertaining the diagnosis of COVID-19 in cancer patients and it is especially true for those with lung cancer, who present additional risk and vulnerability factors, because of tobacco exposure and underlying lung disorders [6,7].

In addition, patients with malignant blood tumors, such as lymphoproliferative neoplasms, are particularly fragile because of immune-depression caused by illness and therapies, which substantially reduce the immune system. Previous studies have shown that influenza infections in immune-compromised patients and with hematological tumors increase mortality and morbidity [8-10]. The greater risk of contracting COVID-19 and developing serious complications could therefore generate significantly higher levels of anxiety, frustration, stress, and fear in cancer patients than in the normal population [11].

Furthermore, it has already been recognized that cancer patients are at greater risk than the general population of developing psychological distress, since cancer is a real threat to life and compromises social, emotional and relational aspects [12-14]. Since little is known about the psychological impact of COVID-19 on cancer patients, the aim of this study was to assess the psychological status of outpatients undergoing anticancer treatment during the Sars-CoV-2 pandemic in a

non-COVID hospital. In particular, we hypothesized that cancer patients treated during the COVID-19 pandemic would exhibit symptoms of anxiety, depression and post traumatic stress disorder.

A further objective was to compare the anxiety and depression levels measured in this emergency period between cancer and non-cancer patients and between cancer patients before and after the emergency assuming an increase in distress in cancer patients in accordance with this period of health emergency.

Methods

Participants

A cross-sectional analysis was conducted on consecutive cancer patients admitted to the IRCCS Istituto Tumori "Giovanni Paolo II" Bari in April 2020, during phase 1 of covid-19. 178 patients were included if they were ≥ 18 years of age; had a diagnosis of lymphoproliferative neoplasm (n.77) (including cHL, NHL, CLL/SLL), lung cancer (n.61) or breast cancer (n.40) and were receiving intravenous chemotherapy and/or immunotherapy. Written consent was obtained from patients participating in the study. The study protocol was approved by the local Ethical Committee.

Participants (51.1% women) ranged in age from 22 to 85 years ($Mean=58\pm 14.4$).

To compare distress levels in the general population, eighty-six non oncological subjects were enrolled as a control group ($Mean=42.30\pm 13$; n. 26 male) in the same period.

The subsample of patients with lymphoproliferative neoplasm has already been object of a previous pilot study [15].

Procedure

Patients were asked to complete the questionnaires by a treating staff member (e.g., nurse practitioner, medical oncologist, psychologist).

A structured self-reporting questionnaire designed for an earlier survey was used to collect epidemiological data and information on any presence of fear, worry and concern due to coronavirus [15].

The first part concerns personal data (age, gender, civil status, school attended, pathology, profession, smoking). The second part includes a brief structured interview investigating the worries regarding the impact of COVID-19 on their lives. The questions were as follows:

1. What is your greatest concern in this period? a) The risk of delaying chemotherapy administration due to COVID-19; b) The risk of getting infected while I am at hospital; c) The risk of infecting my relatives coming back home; d) Potential difficulties in contacting my doctor in the case of need; e) Social distancing from my loved ones; f) Financial difficulties; g) The duration and uncertainty of the situation; h) feeling vulnerable.

2. Have your worries increased during the pandemic? (Answer: Yes; No).
3. Did you feel the need for: a) psychological support; b) homeopathic / herbal remedies; c) drugs for anxiety, insomnia, depression; d) other; e) no help.
4. Did you need on-line psychological support from the Psycho-Oncology Unit of the Hospital? (Answer: Yes; No).

Finally, all patients completed the Impact of Event Scale-Revised (IES-R) [16] and the Hospital Anxiety and Depression Scale (HADS) [17].

The Impact of Event Scale-Revised (IES-R) is a questionnaire used to measure the subjective reaction after a traumatic event. It consists of 22 items organized in three subscales that measure avoidance, intrusion and hyperarousal. Answers range on a scale from 0 (not at all) to 4 (extremely)

The Hospital Anxiety and Depression Scale (HADS) is a questionnaire used to measure anxiety and depression in patients with organic disease, in fact it avoids the use of items related to somatic symptoms. The HADS consists of 14 items, divided into two scales, one for anxiety and one for depression. Responses are rated on 4 levels Likert scale. The scale has good psychometric qualities, also in cancer patients and has been translated and validated in Italian [18].

Both questionnaires related to the previous week.

Descriptive statistics were calculated for sociodemographic characteristics and clinical data. The scores of the IES-R and HADS (HADS-Anxiety; HADS-Depression and HADS-General) were expressed as mean and standard deviation. Correlational analysis was implemented to detect the univariate associations between sociodemographic characteristics, clinical data and the IES-R score as well as the subscales of the HADS. Analysis of vari-

Table 1. Demographic characteristics and rates of mental health outcomes in the sample

	Total N/Mean(% n (%))	Lymphoma N/Mean(% n (%))	Lung Cancer N/Mean(% n (%))	Breast Cancer N/Mean(% n (%))
Age, years			p<0.00 ^a	
Gender				
Women	91 (51)	37 (41)	15 (16)	39 (43)
Men	87 (49)	40 (46)	46 (53)	1 (1)
	n.s.		p<0.00 ^b	
Education				
up to 8 years	25 (17)	2 (8)	18 (72)	5(20)
8- 13 years	90 (60)	43 (48)	24 (27)	23 (25)
>13 years	35 (23)	16 (46)	12 (34)	7 (20)
	p<0.00 ^b		p<0.00 ^b	
Occupation				
Housewife	34 (23)	14 (41)	8 (23)	12 (35)
Unemployed	9 (6)	3 (33.3)	3 (33.3)	?? (33.3)
Employed	53 (34.4)	29 (55)	9 (17)	15 (28)
Retired	57 (38)	12 (21)	39 (68)	6 (11)
Student	1 (0,6)	1 (100)	0	0
	p<0.00 ^b		p<0.00 ^b	
Who do you live with?				
Alone	11 (7.4)	5 (45)	5 (45)	1 (1)
With one family members	71 (47.6)	32(45)	36 (51)	3 (4)
With two or more family members	67 (45)	33 (49)	20 (30)	14 (21)
	p<0.00 ^b		p<0.00 ^b	
HADS				
HADS-D	7.1 (s.d.3.4)	6.1 (s.d.3.3)	8.3 (s.d.2.3)	7 (s.d.4)
HADS-A	8.4 (s.d.4.1)	6,4 (s.d.3.8)	11.3 (s.d.2.6)	8.1 (s.d.3.9)
HADS-G	15.5 (s.d.6.5)	12.5 (s.d.6.3)	19.6 (s.d.3.4)	15.1 (s.d.7.4)
IES				
Intrusion	1.07 (s.d.0.83)	0.90 (s.d.0.70)	1.20 (s.d. 0.93)	1.20 (s.d.0.84)
Avoidance	1.16 (s.d.0.80)	0.96 (s.d.0.67)	1.25 (s.d.0.85)	1.39 (s.d.0.87)
Hyperarousal	2.11 (s.d.1.73)	1.68 (s.d.1.32)	2.43 (s.d.2)	2.44 (s.d.1.84)
IES- Total	1.47 (s.d.1.05)	1.18 (s.d.0.82)	1.68 (s.d.1.21)	1.68 (s.d.1.11)

^at-test; ^bChi-square test. Mean (s.d.) is presented for continuous variables and n(%) for categorical variables

ance was performed to verify the impact of the clinical and socio-demographic factors on the study variables. All tests were two-tailed, with a significance level of $p < 0.05$. Statistical analysis was performed using SPSS Statistic 22.0 (IBM SPSS Statistics, New York, United States).

All data were collected between 15th March and 4th May 2020, the period when Italy was under strict lockdown measures.

In the same period, the HADS and IES-R questionnaires were administered to non-cancer subjects to detect any differences compared to the cancer patients in our sample.

Finally, in 2018 the HADS questionnaire was administered to cancer subjects of the same Institute to detect the presence of depressive or anxious symptom. We used this information to find differences between the two data sets that represent the category of cancer patients at different times.

Results

Patients' clinical and sociodemographic characteristics

One hundred and seventy-eight outpatients were enrolled at IRCCS "Giovanni Paolo II" in Bari. Considering the socio-demographic characteristics of patients, 25 (17%) had a low level of education (up to 8 years), 90 (60%) a medium level (up to 13 years) and 35 (23%) a high level of education. To what concerns the working life, 97 (64.6%) did not work (namely housewives, retired, unemployed or students), 53 (38%) were occupied. Eleven patients (7.4%) lived alone, 71 (47.6%) with one family member, 67 (45%) with two or more family members. Patients' clinical and sociodemographic characteristics, are described in Table 1.

Eighty-six non oncological subjects were enrolled ($Mage=42.30\pm13$; n. 26 male): 11% had a low level of education (up to 8 years), 42% a medium level (up to 13 years) and 47% a high level of education. 9% lived alone, 23% with one family member, 68% with two or more family members. Regarding the working life 50% did not work (namely housewives, retired, unemployed or students), 50% were occupied. Finally the data set regarding the level of Anxiety and Depression in cancer patients two years previously involved 66 patients from the same oncological hospital ($Mage=66\pm8.3$; n.57 male): 67.5% had a low level of education (up to 8 years), 21.5% a medium level (up to 13 years) and 11% a high level of education. As to their working life 72% did not work (namely housewives, retired, unemployed or students), 28% were occupied.

Levels of the HADS and IES-R

The mean HADS-G General Scale score of cancer patients during the COVID-19 period was 15.5

($SD\pm6.5$). We found that 55% (N=95) were above the cut-off (score ≥ 16) for the general scale, 58.4% (N=101) of patients were above the cut-off (score ≥ 8) for HADS-A Anxiety subscale (HADS-A cases), 44% (N=77) of patients were above the cut-off for HADS-D Depression subscale. The mean-IES-R score of patients was 24.8 ($SD\pm17.3$), with 52.1% (N=88) not showing a PTSD diagnosis (score < 23), and 17.7% (N=30) indicating the fulfilment of diagnostic criteria for PTSD at a mild (score 24-32), 6.5% (N=11) moderate (score 33-36) and 23.7% (N=40) severe level (score > 37). Levels of the subscales were the following (dividing the total score by the number of items to arrive at a mean score): Intrusion mean score 1.07 ($SD\pm0.83$), Avoidance mean Score 1.16 ($SD\pm0.80$), Hyperarousal mean score 2.11 ($SD\pm1.73$) (Table 1). In the sample, the hyperarousal symptoms, such as anger and irritability, heightened startle response, difficulty concentrating, and hypervigilance seem to be higher than other ones.

To compare the mean of psychological distress in function of professional role (occupied vs retired) we used a t-test. It is emerged that retired patients have higher levels of anxiety ($F(1, 105)=3.4$, $p<0.005$), and depression ($F(1, 105)=5.6$, $p<0.005$).

There was no correlation between emotional distress (HADS and IES-R scales) and level of schooling and number of cohabitants.

Moreover, by comparing the values between cancer and non-cancer subjects, the non cancer sample has significantly higher values for the depression scales ($t(254)=7.78$; $p<0.001$), general scale ($t(254)=3.9$; $p<0.001$), IES-R ($t(250)=6.99$; $p<0.001$), hyperarousal ($t(250)=7.76$; $p<0.001$), avoidance ($t(250)=4.93$; $p<0.001$), and intrusion ($t(250)=6.56$; $p<0.001$). Instead, no significant differences emerge on the anxiety scale.

By comparing psychological distress levels between cancer patients in 2018 and cancer patients during the COVID-19 period, it emerged

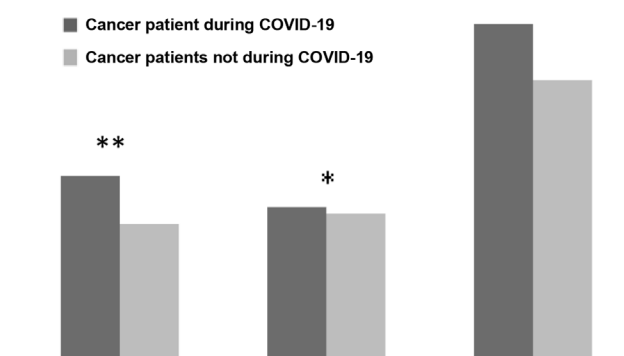


Figure 1. HADS scores in cancer patients during Covid-19 and in not Covid-19 period. * $p<0.05$; ** $p<0.01$

that patients who experienced a health emergency showed significantly higher levels of anxiety (HADS-A, $t(237)=3.73$ $p<0.001$), and general distress (HADS-G, $t(237)=2.51$ $p<0.05$). Instead, no significant differences emerge on the depression scale (Figure 1).

Correlations

The study variables (IES-R, HADS-A, HADS-D and HADS-G) were correlated with all sociodemographic and clinical characteristics of the sample using Pearson's Correlation Coefficient. When age was correlated with the dependent variables, higher levels of HADS (general scale and depression scale) were found in the older age (both $r=0.16$, $p<0.05$). No significance emerged for the IES-R scales.

Moreover, female patients presented higher levels for the IES-R total ($r=0.20$, $p<0.05$), Intrusion ($r=0.17$, $p=0.02$), Avoidance ($r=0.20$, $p<0.05$), Hyperarousal ($r=0.18$, $p=0.02$) compared with males. No significance emerged for the HADS scales.

The HADS general, Depression and Anxiety scales were found to be significantly correlated with IES-R total and with all the subscales of the IES-R, namely hyperarousal, avoidance and intrusion (Table 2).

To verify whether levels of HADS-A, HADS-D, HADS-G and IES-R show differences with the passing of weeks of the lockdown, the first two and the second two weeks of data collection were compared, and it emerged that as the weeks passed the levels of HADS-A and HADS-G increased ($r=0.26$; $p<0.001$, $r=0.23$; $p<0.005$ respectively).

Table 2. Correlation among Hads and IES scores

	HADS-D	HADS-A	HADS-G
IES-Intrusion	0.33**	0.29**	0.36**
IES-Avoidance	0.30**	0.30**	0.34**
IES-Hyperarousal	0.33**	0.34**	0.39**
IES- Total	0.35**	0.33**	0.39**

Pearson's correlation (2-tailed) ** $p<0.01$

Table 3. Mancova diagnosis by age by gender (age as covariate)

Variables	Wilks' Lambda	F	P
Intercept	0.69	13.30	0.000
Age	0.94	1.88	0.10
Gender	0.95	1.30	0.27
Diagnosis	0.75	4.70	0.000
Gender*Diagnosis	0.09	3.28	0.008

Questions on Worry

70% of patients (N=121) declared that their worries increased during the pandemic; their greatest concerns were: I) the risk of getting infected while at hospital (51%, N=89); II) the risk of infecting relatives coming back home (38.9%, N=68); III) the risk of delaying therapy (35.4%, N=62); IV) the social distancing from their loved ones (26%, N=45); V) potential difficulties in contacting the oncologist in case of need (20%, N=35); VI) financial difficulties (12%, N=21).

Studying the questions on worry, it emerged that they are prevalent in the female gender. Specifically, women are more afraid of the risk of getting infected ($X^2(1)=5.47$, $p<0.05$), of delaying therapy ($X^2(1)=4.18$, $p=0.05$) and of the potential difficulties in contacting the oncologist in case of need ($X^2(1)=3.86$, $p<0.05$) compared to men. Furthermore, with the advancement of age the fear of getting an infection decreases ($r=0.23$; $p<0.05$), while those who live with several family members are afraid of infecting relatives ($r=0.17$; $p<0.05$).

They felt the need for Psychological Support (3.4%; N=6); for homeopathic or herbal remedies (3.4%, N=6), for psychotropic drugs (3.9%, N=7) or for other kinds of unspecified support (8%, N=14); but in the face of a heightened need, the majority sought no kind of help (81.5%, N=145).

Comparing different cancer sites

Comparing the levels of depression, anxiety and PTSD depending on the cancer site (lymphoma, lung or breast cancer) significant differences emerged ($F=7.37$, $F=31.37$, $F=4.24$; $p<0.001$ respectively).

The one-way multivariate analysis of covariance (MANCOVA) was used to determine whether psychological distress (HADS scales and IES-R scales) differed, based on diagnosis amongst patients, with gender and cancer site as fixed factors and age as a covariate. The *post hoc* tests were used to determine where these differences occurred between cancer site groups. There was a statistically significant difference between the cancer site groups on the dependent variables (HADS and IES-R) after controlling for age and gender, $F(2, 162)=4.690$, $p<0.0005$, Wilks' $\Lambda=0.751$) (Table 3). Higher levels of depression (HADS-D), anxiety (HADS-A) and general distress (HADS-G) were found in the lung cancer group (Table 1). Analyzing the different means of IES-R-scales it emerged that means of avoidance and hyperarousal are higher in lung and breast cancer than lymphoma diagnosis; the intrusion is more present in lung and breast cancer patients than in lymphoma patients (Table 1).

Discussion

In the present study, we analyzed the psychological status of outpatients coming to our non-COVID Oncological Institute. These patients completed validated questionnaires measuring anxiety, depression and PTSD. Data from the evaluation of one hundred and seventy-eight patients reported that 58% presented anxiety (HADS-A), 44% depression (HADS-D), while 55% was above the cut-off for the HADS-G General Scale; moreover 23% presented several levels of PTSD. These findings may be explained by the fact that the COVID-19 pandemic can be considered as a new form of stressor or trauma that could particularly affect those who are already vulnerable because of biological or psychological burdens, such as cancer patients [19,20]. Specifically, the social isolation imposed during quarantine can increase loneliness and limit social interactions, that are well-known risk factors for psychopathological problems including depression [20]. These stressors may have increased the pre-existing burden of carrying a cancer diagnosis. Women have been found to be more vulnerable to anxiety and to PTSD and this datum is confirmed in previous literature [21,22].

Women are two times as likely as men to develop PTSD after trauma and also experience more severe and constant symptoms, but the basic mechanisms underlying these gender differences are predominantly unknown [23,24].

Comparing the levels of anxiety and depression before and after the COVID-19 emergency, it emerged that the spread of COVID-19 increased the anxiety levels in patients but did not affect the levels of depression. Probably cancer patients often feel depressed throughout the entire course of the disease and the presence of the health emergency did not change the level of anhedonia, and did not affect the main symptoms of pre-existing depression. On the contrary the fear and worry about your own health and the health of your loved ones, your financial situation or job, or loss of support services you rely on and the climate of uncertainty elicited feelings of anxiety as a typical emotion when faced with a feeling of threat.

The prevalence of depression, anxiety and PTSD symptoms varied according to cancer types. Patients with lung cancer were the most prone to experience psychological symptoms, both anxiety and depression.

This could be due to two reasons. Firstly, the poor prognosis of this disease and greater patient burden during treatment causes high distress; in addition, current therapies are still not very effective, and multi-modality treatment approaches are

inevitable [25-27]. Several factors, including high mortality, appear to contribute to high psychological distress in lung cancer. Moreover, the impaired respiratory function within a clinical oncological framework of lung cancer makes the patient likely to feel more vulnerable and to have a greater fear of COVID-19 infection which can cause lung damage [28,29]. The patients with lymphoma have lower distress than others. This datum merits being explored in a larger sample and investigating further variables such as: quality of life, time from diagnosis and stage of disease.

In our sample, anxiety and depression are higher for unemployed and retired people and also for older patients. These patients are more likely to have fewer social relationships, less perceived social support and more problems related to their economic condition [30]. As for elderly cancer patients, our data are only partially supported by the literature. Indeed, numerous studies have shown that elderly cancer patients have a better quality of life than younger patients, especially in terms of psychological well-being [31,32]. However depression in the elderly is often under-recognized and under-treated due in part to the inclination for older people to report depressive symptoms in a different way than younger adults and can be mistaken for signs of aging [33]. This data showed instead that signs of depression have to be well investigated.

Previous studies have compared the prevalence of anxiety and depression in cancer patients by comparing them with those of the general population. The study by Hinz et al [13] highlighted higher levels of anxiety in cancer patients and lower levels of depression in the cancer population than in the general population. The literature data relating to the comparison of depression in cancer patients are not unique. Some reviews reveal a similar risk of depression in cancer patients and the general population, while other studies find greater risks for cancer patients [34,35].

Ringdal and Ringdal [36] compared three groups in terms of depression: people who had cancer at the time of their research, people who previously had had cancer and people who had never experienced cancer. They found that people who were facing a cancer, and those who had previously had cancer showed a greater risk of depression than those who had never had cancer.

However, in our sample, non-cancer subjects have higher levels of depression and PTSD. This data could therefore be attributable to the COVID-19 emergency because the restrictions did not change the routine of patients already undergoing therapies. On the contrary, the emergency completely modified the life of the general population.

Our study has several limitations. First, the limited sample number of patients. Larger-scale studies of cancer patients should be performed. The second limitation is that the study is mono-institutional and our Hospital lies in a Region that is considered at “intermediate incidence” of COVID-19, so the present results may not reflect the trends seen in other parts of the Country. This was a cross-sectional study, which did not allow for an investigation of the patients’ psychological disorder throughout the course of the disease. Therefore, further follow-up studies should be conducted to help understand depressive disorder morbidity and the associated risk factors.

We believe that this study has several strengths. First of all, to our knowledge, there are still no studies in the literature on the effect of the COVID-19 pandemic on the emotional state of cancer patients. Secondly, we evaluated this impact on three groups of patients with different pathologies. Moreover we compared our sample with both the

general population and a group of pre-pandemic cancer patients.

Conclusion

Protecting cancer patients is an important component of public health measures for addressing the COVID-19 epidemic. Special interventions to promote mental well-being in patients in this period of coronavirus disease (COVID-19) need to be immediately implemented, with women, older, and lung cancer requiring particular attention.

Compliance with ethical standards

The study was approved by the local Ethical Committee (reference number: 19_897 CE)

Conflict of interests

The authors declare no conflict of interests.

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