



## Examining the correlation between fear of COVID-19, sexual functions, depression, and anxiety in the women who underwent COVID-19

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### Abstract

This study aimed to examine the correlation between fear of COVID-19, sexual functions, depression, and anxiety in women who have undergone COVID-19. Seventy-five volunteer women who have experienced COVID-19 were included in this study. The sociodemographic characteristics of the participants were obtained using a demographic information form. The Fear of COVID-19 Scale, the Female Sexual Function Index (FSFI), the Female Sexual Distress Scale-Revised (FSDS-Revised), the Patient Health Questionnaire (PHQ-4), and the Global Pelvic Symptom Bother Questionnaire (GPFQB) were used for assessments. Significant, positive correlations were found between the Fear of COVID-19 Scale scores with the FSFI and GPFQB scores ( $p=0.015$ ,  $p=0.005$ ), and significant, positive, and moderate correlations were found between the FSDS-Revised scores with PHQ-4-Anxiety and Depression, PHQ-4-Total, and GPFQB scores ( $p<0.001$ ,  $p=0.002$ ). The findings of this study demonstrate a correlation between the fear of COVID-19 and sexual function, as well as pelvic floor dysfunction in women who have undergone COVID-19. Moreover, a connection was identified between sexual function and sexual distress, anxiety, and depression, as well as between pelvic floor dysfunctions and anxiety and depression in women affected by COVID-19. Consequently, it is suggested that pelvic floor and sexual functions, along with psycho-social states, may be adversely impacted in women infected with COVID-19.

**Keywords:** COVID-19, sexual dysfunction, depression, anxiety.

### 1. Introduction

Throughout history, the world has witnessed various pandemics that have significantly impacted the lives of millions of individuals. Despite advancements in technology and medical research, the emergence of new pathogens continues to pose a threat to the global health system (1-3). In December 2019, a novel virus first appeared in Wuhan, China, and was initially referred to as the New Coronavirus (2019-nCoV). However, due to its close resemblance to SARS-CoV, the World Health Organization renamed the disease SARS-CoV-2 on February 11, 2020, and declared it a pandemic on March 11, 2020 (4,5).

While clinical symptoms typically manifest on the 4th or 5th day following exposure to the infection, studies have indicated that the incubation period may extend up to 14 days (2,6). Despite the majority of infected patients being asymptomatic or experiencing mild symptoms that do not require hospitalization, the overall number of severe cases and fatality rates remain significant (7). COVID-19 is characterized by common symptoms such as fever, cough, dyspnea, and fatigue and is primarily transmitted through direct contact or respiratory droplets, as supported by available evidence. The risk of infection is substantially increased when exposed to droplets expelled through coughing or sneezing, particularly within a one-meter distance from an individual exhibiting

symptoms (8).

When evaluating the symptoms of COVID-19, it becomes evident that cough is a common manifestation. In populations with a higher prevalence of chronic cough, it serves as a significant mode of infection and is associated with an increased incidence of urinary and fecal incontinence, pelvic organ prolapses, and pelvic floor dysfunction. The relationship between pelvic floor dysfunction and cough is attributed to recurrent microtrauma in the pelvic floor due to intra-abdominal pressure (9-11). A previous study involving patients with Chronic Obstructive Pulmonary Disease revealed a frequent occurrence of incontinence, with the severity of incontinence directly proportional to the increased intra-abdominal pressure during coughing (12).

Although urinary incontinence itself may not be life-threatening, it has been suggested to adversely impact the psychological and social well-being of both men and women (13-15). Stress incontinence, as defined by the International Society of Urogynecology and the International Continence Society, refers to urinary incontinence that occurs during coughing, sneezing, or physical exertion (16). Despite the increased likelihood of stress incontinence due to the frequent occurrence of cough in COVID-19, there is a scarcity of studies examining this specific association.

The potential of COVID-19 to affect various bodily systems to differing degrees gives rise to numerous physiological complications. Disabilities not only have a negative impact on an individual's social life during the illness but also persist even after they become medically stable (11). It is widely recognized that the disruption of social life due to COVID-19, along with reduced income and a highly stressful lifestyle, can affect women's sexual desire and frequency of sexual intercourse. Sexual health encompasses the fulfillment of everyone's sexual rights and encompasses physical, emotional, mental, and social well-being. However, strict adherence to social distancing measures and the contagious nature of the disease during the pandemic have adversely affected sexual health (17,18).

While studies conducted during the pandemic have explored the effects on sexual desire, frequency of sexual intercourse, conception, and the use of contraception, we have not come across any literature that evaluates sexual functioning and stress incontinence related to cough in individuals with a medical history of COVID-19. We believe that some underestimated symptoms may include stress urinary incontinence and affected sexual functions in women experiencing cough due to COVID-19. Therefore, the objective of our study is to examine the correlation between fear of COVID-19, sexual functions, depression, and anxiety in women who have undergone COVID-19.

## 2. Materials and Methods

This cross-sectional study involved 75 women and aimed to examine the correlation between fear of COVID-19, sexual functions, depression, and anxiety in women who had previously contracted COVID-19. Participants were recruited from various regions in Türkiye through announcements made on social media platforms such as Facebook, Instagram, WhatsApp, etc. Prior to the commencement of the study, participants were required to provide informed consent, confirming their voluntary participation, and were informed about the study's objectives. Exclusion criteria included pregnancy, recent childbirth, and gynecological surgery within the past six months. Questionnaires intended for the participants were administered electronically via email or text message using Microsoft Forms. A power analysis was conducted to determine the sample size, with a margin of error set at  $0.10 \pm 0.15$  and a confidence interval of 80%, resulting in a required sample size of 75 individuals. The study received the necessary permissions from the Department of Physiotherapy and Rehabilitation in the Faculty of Health Sciences at Izmir Democracy University and from the Ministry of Health. The study protocol was approved by the ethics committee of Izmir Democracy University (Decision No: 2022/03-16).

As data collection tools, we utilized an information form that included personal information such as name, surname, telephone number, and smoking status, as well as demographic

and clinical information including age, obstetric history, gestational week, and educational status. Additionally, standardized questionnaires, including the Fear of COVID-19 Scale, the Female Sexual Function Index (FSFI), the Female Sexual Distress Scale-Revised (FSDS-Revised), the Patient Health Questionnaire (PHQ-4), and the Global Pelvic Symptom Bother Questionnaire (GPFQB) were utilized.

**The Fear of COVID-19 Scale**, developed by Ahorsu et al. in 2020, was designed to assess fear levels associated with COVID-19. It utilizes a five-point Likert-type scale, ranging from 1 (I totally disagree) to 5 (I totally agree), and consists of 7 items representing a single factor. The scale's minimum score is 7, while the maximum score is 35. Higher scores on the scale indicate a greater fear of COVID-19. The Turkish validity and reliability of the scale were established by Artan et al. through a process that involved reviewing scales related to various fear parameters, conducting participant interviews, and seeking expert evaluations (19,20).

**The Female Sexual Function Index (FSFI)** is a Likert-type scale consisting of 19 items. FSFI's validity and reliability study was developed by Rosen et al. It assesses sexual dysfunction. It encompasses six sub-dimensions, namely sexual desire (questions 1 and 2), arousal (questions 3, 4, 5, and 6), lubrication (questions 7, 8, 9, and 10), orgasm (questions 11, 12, and 13), satisfaction (questions 14, 15, and 16), and pain (questions 17, 18, and 19). Each question evaluates the sexual function of women within the past four weeks. The scale provides a range of raw scores from 4 (lowest) to 95 (highest). After multiplying the coefficients, the total score ranges from 2 (lowest) to 36 (highest). The optimal cut-off value for women is considered to be 26.55, with scores above 26.5 indicating normal sexual function, while scores below 26.5 suggest sexual dysfunction. The Turkish validity and reliability study of the FSFI was conducted by Aygin and Aslan in 2005 (21,22).

**The Female Sexual Distress Scale-Revised (FSDS-Revised)**, developed by Derogatis et al., is designed to assess sexually-related personal distress in women. The scale was adapted to Turkish by Aydın et al., who also conducted the validity and reliability study. Comprising 13 items, the FSDS-Revised evaluates various aspects of distress related to sexual activity in women. Participants respond to the items using a 4-point Likert-type scale, with choices ranging from never (0) to rarely (1), sometimes (2), often (3), or always (4). The minimum score that can be obtained on the FSDS-Revised is 0, while the maximum score is 52. Higher scores indicate higher levels of sexual distress. In the Turkish version of the scale, a cut-off point of  $\geq 11$  is accepted to determine the presence of sexually-related personal distress in women (23,24).

**The Patient Health Questionnaire (PHQ-4)**, developed by Kroenke et al. in 2009, is a Likert-type scale that assesses depression and anxiety. The Turkish validity and reliability of this questionnaire, consisting of two sub-dimensions,

depression and anxiety, were established by Demirci and Ekşi in 2018. To calculate the anxiety sub-dimension score, items 1 and 2 in the questionnaire are summed. The depression sub-dimension score is calculated based on items 3 and 4. The PHQ-4 total score ranges from 0 to 12. A score of 0-2 indicates no psychological stress, 3-5 indicates mild psychological stress, 6-8 indicates moderate psychological stress, and 9-12 indicates severe psychological stress (25,26).

**The Global Pelvic Floor Symptom Bother Questionnaire (GPFBQ)**, developed by Peterson et al. in 2010, assesses various dysfunctions related to the pelvic floor, including a sudden urge to urinate, dyspareunia, stress and urge urinary incontinence, voiding difficulty, frequent urination, pelvic organ prolapse, obstructive defecation, and anal incontinence. The questionnaire consists of 9 questions. Participants respond to the questions by indicating "yes" or "no" (0), depending on the presence or absence of the symptom. If the response is "yes," they rate their discomfort on a scale ranging from "not at all" (1) to "a lot" (5). The total score ranges from 0 to 45; the mean score is calculated and multiplied by 20 to obtain a score between 0 and 100. A higher score on the questionnaire indicates greater dysfunction. The Turkish validity and reliability analysis of the questionnaire was conducted by Doğan (27,28).

### 2.1. Statistical analysis

The statistical analysis was conducted using the SPSS 15.0 program. Descriptive statistics, including numbers, frequencies, means  $\pm$  standard deviation, and medians (minimum-maximum), were calculated for the obtained measurements and presented in tables. The normal distribution of numerical variables in each group was assessed using the Kolmogorov-Smirnov and Shapiro-Wilk tests. As the values, except for the Fear of COVID-19 Scale scores, did not follow a normal distribution, Spearman Correlation Analysis was performed to examine the relationships between variables. The strength of the correlations was determined as strong ( $r_s \geq 0.70$ ), moderate ( $r_s = 0.40-0.69$ ), and weak ( $r_s \leq 0.39$ ) based on the results of this analysis (29). The statistical significance level for the study was set at  $p < 0.05$ .

### 3. Results

A total of 75 women, with a mean age of  $37.88 \pm 13.094$  years, were included in the study. Table 1 presents the demographic characteristics of the participating women. The median age was 36 years (range: 19-73), the mean height was  $1.63 \pm 0.059$  meters, the median body weight was 64 kg (range: 45-132), and the median body mass index (BMI) was  $24.22 \text{ kg/m}^2$  (range: 18.08-49.08) (Table 1).

Table 2 presents the correlations between the scale scores of the participants. The results of the analyses revealed several statistically significant correlations. There were statistically significant, positive, and weak correlations between the Fear of COVID-19 Scale scores with the FSFI and GPFBQ scores ( $p = 0.015$ ,  $p = 0.005$ ). Furthermore, a statistically significant,

positive, and weak correlation was found between the FSFI and FSDS-Revised scores ( $p = 0.003$ ). Additionally, statistically significant correlations were observed between the FSDS-Revised scores and the PHQ-4-Anxiety, PHQ-4-Depression, PHQ-4-Total, and GPFBQ scores ( $p < 0.001$ ,  $p = 0.002$ ). Notably, statistically significant correlations were found between the PHQ-4-Anxiety scores with the PHQ-4-Depression, PHQ-4-Total scores, and GPFBQ scores ( $p \leq 0.001$ ). Moreover, statistically significant correlations were observed between the PHQ-4-Depression scores with the PHQ-4-Total scores and GPFBQ scores ( $p < 0.001$ ,  $p = 0.038$ ). Lastly, a statistically significant, positive, and weak correlation was found between the PHQ-4-Total and GPFBQ scores ( $p = 0.006$ ).

**Table 1.** Descriptive characteristics of individuals

Descriptive Characteristics	Individuals (n=75)
	$\bar{x} \pm \text{SD}$ / median (min-max)
Age (year)	36 (19-73)
Height (m)	$1.63 \pm 0.059$
Weight (kg)	64 (45-132)
Body mass index ( $\text{kg/m}^2$ )	24.22 (18.08-49.08)
Time after COVID-19 disease (month)	3 (0.10-19)
Working status (n; %)	
Working	52; 69.4%
Not working	23; 30.6%
Education level (n; %)	
Primary school	2; 2.7%
High school	14; 18.7%
Higher education	59; 78.7%
Marital status (n; %)	
Single	21; 28%
Married	54; 72%
Cough condition during COVID-19 disease (n; %)	
Yes	58; 77.3%
No	17; 22.7%
Urinary incontinence during COVID-19 disease (n; %)	
Yes	11; 14.7%
No	64; 85.3%

m: meter, kg: kilogram, n: frequency, %: percentage,  $\bar{x} \pm \text{SD}$ : mean  $\pm$  standard deviation, min: minimum, max: maximum.

**Table 2.** The relationship between the scale scores of the individuals

Individuals (n=75)		Fear of COVID-19 Scale	Female Sexual Function Index	Female Sexual Distress Scale-Revised	Patient Health Questionnaire-4-Anxiety	Patient Health Questionnaire-4-Depression	Patient Health Questionnaire-4-Total	Global Pelvic Symptom Bother Questionnaire
1.Fear of COVID-19 Scale	r <sub>s</sub>	-	<b>0.279</b>	0.219	0.150	0.086	0.132	<b>0.320</b>
	p		<b>0.015*</b>	0.059	0.200	0.465	0.259	<b>0.005</b>
2.Female Sexual Function Index	r <sub>s</sub>	-	-	<b>0.335</b>	0.201	0.092	0.140	0.170
	p			<b>0.003*</b>	0.083	0.434	0.230	0.145
3.Female Sexual Distress Scale-Revised	r <sub>s</sub>	-	-	-	<b>0.495</b>	<b>0.350</b>	<b>0.428</b>	<b>0.508</b>
	p				<b>&lt;0.001*</b>	<b>0.002*</b>	<b>&lt;0.001*</b>	<b>&lt;0.001*</b>
4.Patient Health Questionnaire-4-Anxiety	r <sub>s</sub>	-	-	-	-	<b>0.828</b>	<b>0.947</b>	<b>0.361</b>
	p					<b>&lt;0.001*</b>	<b>&lt;0.001*</b>	<b>0.001*</b>
5.Patient Health Questionnaire-4-Depression	r <sub>s</sub>	-	-	-	-	-	<b>0.959</b>	<b>0.240</b>
	p						<b>&lt;0.001*</b>	<b>0.038*</b>
6.Patient Health Questionnaire-4-Total	r <sub>s</sub>	-	-	-	-	-	-	<b>0.312</b>
	p							<b>0.006*</b>
7.Global Pelvic Symptom Bother Questionnaire	r <sub>s</sub>	-	-	-	-	-	-	-
	p							

n: frequency, r<sub>s</sub>: Spearman correlation coefficient, \*p<0,05

#### 4. Discussion

The present study revealed significant correlations between fear of COVID-19 and sexual function as well as pelvic floor dysfunction. Additionally, correlations were found between sexual function and sexual distress, anxiety, and depression; and between pelvic floor dysfunctions and anxiety and depression in women infected with COVID-19. These findings suggest that the pelvic floor and sexual functions, along with the psycho-social states, may be affected in women who have contracted COVID-19.

The anal and urethral sphincters are innervated by the pudendal nerve. Inflammation or demyelination of the pudendal nerve, which may occur due to COVID-19, can lead to bladder and bowel incontinence (30). Furthermore, existing literature reports an increased frequency of urination in individuals with COVID-19, and there are studies exploring telemedicine applications for patients with urinary

incontinence issues (1,31). The incidence of urinary incontinence is higher in populations with a higher prevalence of chronic cough and increases with age and obesity (32). Frequent and high levels of intra-abdominal pressure due to coughing can lead to recurrent microtrauma in the pelvic floor. Although there is limited evidence, COVID-19, characterized by symptoms such as shortness of breath and recurrent cough, may contribute to pelvic floor insufficiency and consequently result in urinary incontinence (11).

In our study, 77.3% of the participants reported having a cough during their illness, while 14.7% of them reported experiencing urinary incontinence due to COVID-19, which is consistent with the existing literature. Coughing is known to be a significant trigger for stress urinary incontinence, and considering that most participants reported cough-related complaints, we believe that coughing may have contributed to the development of incontinence in these individuals.

Although we anticipated a higher incidence of urinary incontinence during COVID-19, we speculate that the relatively young age and normal body mass index of the participants had a protective effect against urinary dysfunction. In our assessment using the GPFHQ, we specifically inquired about urinary incontinence in the past month, and the prevalence was determined to be 25%. We hypothesize that both the early and late symptoms documented in the literature following COVID-19, as well as other comorbidities experienced by the participants, could potentially contribute to the occurrence of urinary incontinence in the later stages of the disease.

Various measures, such as mandatory lockdowns, were implemented during the pandemic to mitigate the spread of COVID-19. While these measures have been effective in curbing the transmission of the virus, they have also had significant repercussions, including the cessation of social gatherings, the closure of businesses, and widespread financial hardships resulting from job losses (33). The challenges brought about by COVID-19 have not only posed physical health problems but have also given rise to a psycho-social crisis (34). Previous studies investigating the impact of disasters on mental health have demonstrated that large-scale traumatic events accompanied by economic and social consequences are associated with an increased mental burden (33). The pandemic has not only heightened public health concerns but has also contributed to the emergence of significant psychological distress, including avoidance behaviors and post-traumatic stress disorder (35).

In recent years, social isolation and imposing restrictions on personal freedoms have significantly altered people's attitudes toward life and health-related behaviors. The losses incurred due to COVID-19 have sparked a heightened awareness of mortality and existential anxiety (36). The pandemic's profound disruptions to daily life, apprehension about personal and loved ones' health, and overall uncertainty about the future contribute to stress factors. The response to stress can vary based on gender, with women often being the most affected during humanitarian crises such as pandemics, wars, or natural disasters (33,34,37). Women bear a heavier physical and psycho-social burden than men due to the demands of multiple social roles, including childcare, elderly care, occupational and academic responsibilities, household chores, and other obligations (38). With the closure of schools due to quarantine measures, it is anticipated that the workload for women has increased. A study reported a significant surge in violence against women during the lockdown period. The unequal societal norms and gender roles further illustrate that women are affected by the pandemic to a different extent than men (34). Additionally, factors such as socioeconomic vulnerability, tobacco use, exposure to interpersonal violence, social exclusion, and excessive exposure to information can contribute to a heightened perception of fear during the pandemic (38).

In the COVID-19 pandemic process, changes in social life through prolonged quarantine periods, increased anxiety and depression have brought together sexual dysfunction. Bhambhani et al. (39) examined sexual function and frequency in women, and it was reported that while there was no change in the frequency of sexual function, there was an increase in sexual dysfunction. In the studies, moderate and high levels of fear of COVID-19, which may contribute to increased stress burden and mental distress, were reported, and in a descriptive study conducted on 400 married couples, it was found that fear of COVID-19 harmed the sexual functions of married women and could reduce the quality of life in married individuals (40,41). Despite the fact that sexual dysfunction is not listed as the primary complaint by the individuals who underwent COVID-19, it has been observed as a worsening problem in women during the pandemic period (42). It is thought that COVID-19 infection causes similar inflammatory changes in the pelvic organs as well as its effects on the body. In addition, existing pelvic floor dysfunctions have become more evident in the pandemic due to the limitation of physical activity in daily life and other reasons (42). In a study conducted by Carlin et al. (43), it was found that the COVID-19 pandemic significantly increased the dysfunction in women who had pelvic floor dysfunction. In our study, the change in the women's sexual functions due to COVID-19 was evaluated with the FSFI, which included six sub-parameters. It was observed that the infection of the participants caused a decrease in their sexual functions, and women reported moderate levels of pelvic floor dysfunction, according to the GPFHQ.

Sexual health requires not only women's physical well-being but also their emotional and mental well-being. While the increased fear due to COVID-19 may cause physiological and hormonal changes in the body, the fear of catching COVID-19 may negatively affect a person's sexual functions.

In the current study, we found that there were positive correlations between the fear of COVID-19, sexual functions, pelvic floor dysfunctions, and psychological influences of the participants. We consider that such states as recurrent cough, dyspnea, decrease in physical activity, fear, and anxiety may be effective in revealing their pelvic floor dysfunctions.

During any contagious disease pandemic, the psychological reactions of society play an important role in both shaping the spread of the disease and the emergence of emotional distress and social disorder during and after the pandemic (44). In particular, the couples who experienced more conflict due to living together all the time during the pandemic reported engaging in less intimate relationships and sexual intercourse with their spouses (45). In a study, half of the sample reported a decrease in the frequency of sexual intercourse during the quarantine period due to two possible reasons: distress due to quarantine and inability to reach a preferred sexual partner. Another study conducted on COVID-19 concluded that social distancing negatively affected sexual

activity (46). In the literature, it has been documented that adequate sexual activity is positively associated with psychological well-being, and it affects sexual health in a positive way (47). In a systematic review of 34 articles from 18 countries, the issues ranging from cognitive, emotional, and personality factors affecting sexual life during the pandemic to factors such as relationships, bringing up children, and employment status during this period were discussed, and it was found that women experienced more sexual problems than men during the COVID-19 pandemic, including low sexual desire and low sexual satisfaction. In most of the studies, it was concluded that while decreases in the frequency of sexual intercourse occurred during the pandemic, high levels of stress could also be a major contributor to sexual dysfunction (17).

In our study, it was found that the participants reported mild levels of stress. Literature suggests that emotions are related to sexual problems. Therefore, we believe that the stress reported by the participants may be related to sexual dysfunction and sexual distress. While sexual activity has positive effects on psychological well-being and sexual health, the presence of emotional distress, such as stress and anxiety, may lead to a decrease in sexual intercourse frequency.

As post-COVID-19 patients may be more prone to anxiety and post-traumatic stress disorder-type symptoms, it is important for physiotherapists to assess their patients' mental health concerns. Anxiety can increase the risk of urgent and frequent urination and place them at higher risk for constipation by overloading the patient's sympathetic nervous system. In addition, anxiety can lead to excessive activity and pain in the pelvic floor by causing a chronic gripping pattern in the pelvic floor muscles (11). Although patients with pelvic floor dysfunction are not under a life-threatening risk, it is well-known that they face limitations in their daily lives, which negatively affect their quality of life, including social, emotional, and sexual well-being (43).

In the results of our study, it was observed that there was mild anxiety and depression in the participants, and there was a correlation with GPFBQ. We also consider that the reason for the mild course of anxiety and depression due to COVID-19 may be owing to the fact that the participants did not experience severe symptoms when they were infected and/or due to their demographic characteristics.

As a result of our study, we believe that the pelvic floor, sexual functions, and psycho-social state may be affected in women who have undergone COVID-19. Microtraumas that may occur due to increased intra-abdominal pressure and the restriction of physical activity in daily life may play a significant role in the emergence of pelvic floor dysfunction.

While dysfunction in the pelvic floor negatively affects both sexual activity and psychological well-being in women, such psychological influences as anxiety and depression can also decrease sexual functions in women. Together with the

fact that sexual function and pelvic floor problems are among the issues that women have difficulty talking about in our society, its correlation with the psycho-social state is also supported by the literature. Even if they are not included in the main symptoms of COVID-19, these dysfunctions are very important in human life, especially in the individual's quality of life. For this reason, there is a need for educational programs and more research in order to be able to ensure public awareness.

There were some limitations in our study. Since the current study included women in Turkey, the participants could not be evaluated face-to-face. Instead, they were evaluated on the Internet through Microsoft Forms. Another limitation was that the chronic diseases of the participants were not questioned. In addition, the absence of a control group in the present study was another limitation.

#### **Conflict of interest**

The authors declared no conflict of interest.

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None to declare.

#### **Authors' contributions**

Concept: Ö.Ç.Ö., B.Y., K.Ö., Design: Ö.Ç.Ö., B.Y., K.Ö., Data Collection or Processing: Ö.Ç.Ö., B.Y., K.Ö., Analysis or Interpretation: Ö.Ç.Ö., B.Y., K.Ö., Literature Search: Ö.Ç.Ö., B.Y., K.Ö., Writing: Ö.Ç.Ö., B.Y., K.Ö.,

#### **Ethical Statement**

Approval was obtained from Izmir Democracy University Non-Invasive Clinical Research Ethics Committee, the study started. The ethics committee decision date is 23/02/2022 and the number of ethical committee decisions is 2022/03-16.

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