Application of the Stress and Anxiety to Viral Epidemic-6 (SAVE-6) and Coronavirus Anxiety scales (CAS) to measure cancer patient anxiety in response to the COVID-19

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ABSTRACT

This study investigated the usefulness of the 6-item Stress and Anxiety to Viral Epidemics (SAVE-6) scale and the Coronavirus Anxiety Scale (CAS) as tools to assess anxiety related to coronavirus disease (COVID-19) in cancer patients. A total of 221 patients with cancer responded to an anonymous online questionnaire between July 15 and August 15, 2020. The functional impairment of the patients was assessed using the Work and Social Adjustment Scale (WSAS), and the SAVE-6 and CAS were also applied. Among these 221 cancer patients, 110 (49.8%) had SAVE-6 scores ≥ 15 and 21 (9.5%) had CAS scores ≥ 5 . Within the study population, 104 (47.1%) and 29 (13.1%) patients had WSAS scores ≥ 11 (moderate to severe functional impairment) and ≥ 21 (severe functional impairment), respectively. The correlations between the SAVE-6 and WSAS ($p < 0.001$) and CAS ($p < 0.001$) scores were statistically significant. The cut-off for the SAVE-6 was 15 points, while that for the WSAS was 11. Our results suggested that the SAVE-6 and CAS could be used to evaluate moderate and severe degrees of functional impairment related to mental health, respectively, in cancer patients during viral epidemics.

Key words: anxiety, mental health, cancer, COVID-19

INTRODUCTION

Coronavirus disease (COVID-19), which is caused by the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) that originated in the Hubei province of China in December 2019, has spread rapidly worldwide (1) and been declared a global pandemic by the World Health Organization (2). **The widespread contagion and lockdown of the COVID-19 have caused considerable mental health problems such as anxiety, depression and post-traumatic stress symptoms (3-6). Different levels of psychological distress may appear depending on the healthcare workers (6-9), the elderly (10), and the presence of underlying disease (11).**

Cancer diagnosis and treatment is a major stressor resulting in considerable mental health issues for patients, such as anxiety and depression (12). Compared with general populations, cancer patients are at a higher risk of mental health problems (13-15). Therefore, cancer patients may be more vulnerable to mental health problems.

In a recently published study of the cancer patients in China during the COVID-19 pandemic, patients reported adverse psychiatric symptoms with the highest percentages accounted for by depression, anxiety, and PTSD which were 23.4%, 17.7%, and 9.3%, respectively (11). Even in normal times, fear and anxiety affect the course of underlying diseases (16). Patients with cancer undergoing active treatment or taking immunosuppressive medication are more vulnerable to viral infection (17, 18). Previous studies demonstrated the potential impacts of COVID-19-related anxiety on decision-making processes such as increased procedures and surgical refusal (16), and

chemotherapy postponement (19). COVID-19 has caused oncology departments to act and adopt newly-devised guidelines for cancer care (20). Therefore, it is important to evaluate virus-related anxiety in cancer patients.

Despite the significance of viral epidemics, evaluating psychiatric symptoms without consideration of pandemic could limit its impact. Therefore, a specific instrument to measure mental health problems is needed in cancer patients under pandemic era. There are several scales that assess mental health problems related to viral epidemics. However, to our knowledge, there have been no studies validating these scales with the cancer patient sample.

The 6-item Stress and Anxiety to Viral Epidemics (SAVE-6) (21), one of scales that measure the anxiety related to viral epidemics, is a self-report questionnaire.

SAVE-6 was shown to sensitively detect people with non-pathological psychological problems and stresses (22). **It was validated among the healthcare workers sample, but not among the other samples.** The Coronavirus Anxiety Scale (CAS) is a 5-item self-report questionnaire that first published mental health screening tool to identify individuals with functional impairment due to COVID-19 (23). Lee and researchers in other countries conducted a series of follow-up studies to validate the CAS and demonstrate its psychometric properties with solid reliability and validity (24-27). While developing and validating the SAVE-6 to examine the anxiety and worries regarding the coronavirus among cancer patients in South Korea, we also included the CAS to examine how these two measures can be applied to this population.

Considering the above, this study aimed to (1) screen for anxiety response to viral epidemics among cancer patients using the SAVE-6 and CAS, (2) examine the validity of the SAVE-6 among cancer patients, and (3) to explore the appropriate cut-off

score of the SAVE-6 as a useful tool for measuring the degree of functional impairment.

METHODS

1. Participants

In the current pandemic era, this study administered a **cross-sectional** online survey to cancer patients who visited Asan Medical Center, Seoul, Korea, between July 15 and August 15, 2020. **Asan Medical Center is one of the largest cancer centers in Korea. We advertised cancer patients who attended outpatient clinics of the Departments of Oncology, General Surgery, Radiation Oncology, and Asan Cancer Edu-Info Center regardless of their specific tumor were included consecutively. Inclusion criteria in addition to presence of a cancer disease were age 18 years and voluntary participation in the study. The subjects were able to see our advertisement in the hospital the study's objectives, enrollment procedure, and the survey's anonymous online design for measuring cancer patient's anxiety in response to viral epidemics, and they were able to respond quickly by clicking the relevant link. The 221 responders completed this survey. The survey collected information on patient age, sex, and marital status and cancer type, illness duration, cancer stage, and current treatment modalities. The survey also included three additional questions: "Have you experienced or been treated for depression, anxiety, or insomnia?" (Currently under treatment, Have been treated in the past, Never been treat) to assess the past or current psychiatric history, "Do you feel that you are currently depressed or anxious, or do you need help for your mood state?" (Yes, No) to check patients' current needs of being helped by a psychiatrist, and "Are you more afraid of coronavirus than can-**

cer?" (No:0-Yes:10) to measure the severity of afraid of coronavirus than cancer in this pandemic era.

The subjects were provided an e-gift coupon valued at approximately 3 dollars for their participation. The study protocol was approved by the Institutional Review Board, which waived the requirement for written informed consent (No. 2020-1055).

2. Rating scales

1) SAVE-6 scale

The SAVE-6, a self-administered, six-item questionnaire, assesses general anxiety response to viral epidemics. The SAVE-6 has been derived from the original SAVE-9 scale (www.save-viralepidemic.net) to assess work-related stress and anxiety responses of healthcare workers to the COVID-19 viral epidemic (22). The SAVE-9 was clustered into two factors; 1) anxiety response to viral epidemics and 2) work-related stress. Factor 1 of the SAVE-9, termed SAVE-6, extracted for the general population. The scale includes six items: 1) Are you afraid the virus outbreak will continue indefinitely? 2) Are you afraid your health will worsen because of the virus? 3) Are you worried that you might get infected? 4) Are you more sensitive towards minor physical symptoms than usual? 5) Are you worried that others might avoid you even after the infection risk has been minimized? 6) Do you worry your family or friends may become infected because of you? Respondents rated their agreement with each item on 5-point scales as follows: 0 (never), 1 (rarely), 2 (sometimes), 3 (of-

ten), and 4 (always). **Previous study (21) used** a cut-off score of the SAVE-6 was 15 based on the least mild degree (≥ 5 points) of the General Anxiety Scale-7 (GAD-7).

2) Coronavirus Anxiety Scale (CAS)

The CAS is a brief self-reported mental health screening tool for clinical anxiety and fear associated with the COVID 19 crisis or the so-called “coronaphobia” that was developed by Lee (23). This five-item scale measures dizziness, sleep disturbance, tonic immobility, appetite loss, and abdominal distress on a five-point scale from 0 (not at all) to 4 (nearly every day) based on symptoms over the past 2 weeks. The original CAS investigation showed solid reliability ($\alpha=.92$) and validity in a sample of 775 adult residents in the US. The optimized cut-off score of ≥ 9 (90% sensitivity and 85% specificity) discriminated between persons with and without dysfunctional anxiety. However, Lee’s replication study proposed to lower the CAS cut-off score to ≥ 5 for the general public as the sample in his original investigation comprised exclusively adults anxious about the coronavirus, whereas the sample in the replication study did not require experience related to COVID-19 (27). **The psychometric properties of the CAS have been verified in South Korea (28). Cronbach’s alpha for this study sample was 0.85.**

3) Work and Social Adjustment Scale (WSAS)

The WSAS is a self-reported scale of functional impairment due to an identified problem developed by Marks (29) and widely used to quickly assess patients reporting functional impairment due to depression, anxiety, or alcohol misuse disorders. The current form

of WSAS is a five-item scale that measures 1) the ability to work or study; 2) home management; 3) social leisure activities, 4) private leisure activities; and 5) the ability to maintain close relationships. Each item is rated on a nine-point Likert scale from 0 (not at all) to 8 (severely impaired). Total sum scores below 10 suggest a subclinical population, while scores ≥ 11 and ≥ 21 indicate significant but not severe and moderately severe to severe functional impairment, respectively (29). **For the purpose of our study, we used a Korean version of the WSAS that created and translated in previous studies (28, 30), with the author's permission.**

3. Statistical analysis

All statistical analyses were performed using IBM SPSS Statistics for Windows, version 21.0 (IBM Corp., Armonk, NY). The clinical characteristics were summarized as means $\pm$ standard deviation. **For the corrections due to the occurrence of multiple comparisons among/between the SAVE-6, CAS, and WSAS, statistical significance was specified using a Bonferroni correction.** Therefore, a two tailed p-value of <0.0167 (which= $0.05/3$ outcome variables) was defined as statistically significant. **First, principal component analysis was done to explore the confirmatory factors of SAVE-6, and also performed.** Second, **Spearman's correlation test was used to evaluate the correlation between SAVE-6 and other scales, since those scales scores were not normally distributed.** ~~Student's t-tests for continuous variables and chi-square tests for categorical variables were performed.~~ **And last,** Receiver operating characteristic (ROC) analysis was performed to determine the appropriate cut-off points of the SAVE-6

using the WSAS to explore the usefulness of the SAVE-6 as a functional impairment assessment tool.

RESULTS

The demographic characteristics of the study participants are summarized in Table 1.

The mean age of the 221 patients who participated in this study was 50.1 ± 13.3 years.

Of these, 168 (76%) patients were female and were younger than the male patients (48.7 ± 12.6 vs. 54.6 ± 14.9 years, $p < 0.001$). The cancer included breast (n=89, 40.3%), colorectal (n=23, 10.4%), gastro-esophageal (n=20, 9.0%), lung (n=15, 6.8%), pancreas and biliary tract (n=11, 5.0%), head and neck (n=11, 5.0%), hematologic (n=9, 4.1%), liver (n=8, 3.6%), urinary tract (n=7, 3.2%), gynecologic (n=6, 2.7%), kidney (n=4, 1.8%), thyroid (n=4, 1.8%), and others including dual diagnosis (n=14, 6.3%). **Breast (n=89, 40.3%) was the most prevalent cancer followed by colorectal (n=23, 10.4%), and gastro-esophageal (n=20, 9.0%).** Twenty (9.0%) patients had experienced or had been treated for depression, anxiety, or insomnia and 49 (22.2%) patients believed that they were depressed or anxious reported needing help for their mood state.

Among 221 cancer patients, 110 (49.8%) had SAVE-6 scores ≥ 15 (21), while only 21 (9.5%) had CAS scores ≥ 5 (27). A total of 104 (47.1%) subjects had WSAS scores ≥ 11 (moderate to severe dysfunction) and 29 (13.1%) had WSAS ≥ 21 (severe dysfunction) (29).

Principal component analysis revealed that all of 6 items in the SAVE-6 can be clustered into one factor (factor loading value 0.468 ~ 0.819). The Cronbach's alpha of the 6 items was 0.804. We adopted one-factor structure based on the goodness-of-fit (Bartlett's test of sphericity, $p < 0.001$; Kaiser-Meyer-Olkin = 0.795). The ROC analysis

showed a SAVE-6 cut-off score of ≥ 15 for moderate to severe functional anxiety (≥ 11) based on the WSAS (area under the ROC curve [AUC]=0.750, sensitivity=0.69, specificity=0.68). The proportions of participants with various SAVE-6, WSAS, and CAS scores are shown in Figure 1.

The Spearman correlation test showed positively significant correlations between SAVE-6 scores and WSAS ($\rho = 0.48$, $p < 0.001$), CAS ($\rho = 0.32$, $p < 0.001$), and the visual analog score regarding feeling more afraid of coronavirus than cancer ($\rho = 0.17$, $p = 0.01$).

DISCUSSION

In this study, we observed anxiety responses to the COVID-19 pandemic in half (49.8%) of cancer patients (SAVE-6 ≥ 15), while 9.5% showed 'dysfunctional anxiety' (23) associated with the COVID-19 crisis (CAS ≥ 5). Furthermore, 47.1% and 13.1% of cancer patients had moderate to severe (WSAS ≥ 11) and severe (WSAS ≥ 21) 'functional impairment associated with mental disorder' (29), respectively. The appropriate cut-off score of SAVE-6 was 15 for moderate to severe degrees of dysfunction (≥ 11) in the WSAS.

Our previous study on the development of the SAVE-9 scale among healthcare workers (21) identified a SAVE-9 scale score cut-off for mild general anxiety as a Generalized Anxiety Disorder-7 items (GAD-7) scale score of ≥ 5 . We observed that 21 points in the SAVE-9 scale and 15 points in the anxiety subcategory of the SAVE-9 (SAVE-6) were appropriate for mild anxiety symptoms among healthcare workers. This study explored the appropriate SAVE-6 cut-off score for moderate functional impairment related to mental health among cancer patients, for which a cut-off of 15 points was appropriate. A total of 110 (49.8%) patients had SAVE-6 scores ≥ 15 , while 104 (47.1%) had WSAS scores ≥ 11 . The degrees of functional impairment in work, social and private leisure activities, home work, and social relations can sensitively reflect the changes and severity of mental illness (31). We demonstrated that the SAVE-6 could be used to assess viral epidemic-specific psychological status in subjects not screened by the GAD-7 and WSAS. With more than 47% of cancer patients being affected, this should not be overlooked as the COVID-19 pandemic has been on-going for more than 6 months.

For a CAS cut-off score of ≥ 5 points, 9.5% of cancer patients showed dysfunctional anxiety regarding COVID 19, a finding well-supported by Lee's replication study (27). Although the original study describing the CAS proposed a dysfunctional anxiety cut-off score of ≥ 9 points, the subsequent study suggested lowering this cut-off to ≥ 5 points, corresponding to a sensitivity and specificity of 71% and 74% respectively, which showed acceptable diagnostic value. This change was proposed mainly because the participants of the original study were exposed not only to media coverage of coronavirus for at least 1 hour during the previous two weeks but also reported significant anxiety and fear regarding the COVID 19 outbreak in the early stages. The cut-off score was suggested to be lowered to ≥ 5 for the general public ~~including cancer patients~~ in South Korea, where the coronavirus has been better controlled than in the US. This was consistent with 13.1% of cancer patients meeting the WSAS cut-off score of ≥ 21 .

The reduced CAS cut-off score may be associated with the purpose and characteristic of the measure. While the CAS was designed to screen people with functional impairment caused by the coronavirus pandemic mainly through their somatic symptoms, the SAVE-6 was developed to identify cancer patient anxiety regarding COVID-19 based on their emotional states. Thus, a scale that measures physical symptoms may better screen people with more severe anxiety than those with just emotional states. Thus, it is plausible that among 221 cancer patients, 110 (49.8%) had SAVE-6 scores ≥ 15 (21), while only 21 (9.5%) had CAS scores ≥ 5 .

This study has the biases inherent to anonymous online questionnaires. Although face-to-face clinical interviews may have been helpful to evaluate psychiatric symptoms, it was not easy to interview cancer patients during the pandemic era with minimal contact. **Additionally, sampling of our study was voluntary. The responses might also**

be biased, as this study utilized a self-reported survey. Older populations (greater than 65 years) were underrepresented in this online-based survey and most participants were women and breast cancer patients from one hospital in South Korea. Therefore, the generalizability of the results of this study to all patients with cancer may be limited.

In conclusion, the SAVE-6 scale can be applied to cancer patients to measure moderate functional impairment related to mental health due to anxiety concerning the COVID-19 outbreak. The CAS scale, as suggested by the original developer (23), can be applied to cancer patients to assess severe functional impairment related to mental health.

Data Availability Statement

The datasets generated for this study are available on request to the corresponding author.

Author Contributions

MHA, JL, and SC conceived the study. SC obtained ethic approval. SS and SL recruited participants and obtained data. YS organized the database. HJK performed statistical analyses. All authors contributed to the article and approved the submitted version.

Conflict of Interest

The author declares that there is no conflict of interest.

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Table 1. Subjects' demographic characteristics (N=221)	
Variables	
Sex (female)	168 (76.0%)
Age (years)	50.1 ± 13.3
Marital status (single / married)	39 (17.6%) / 178 (80.5%)
Years from initial cancer diagnosis (years)	3.3 ± 3.5
Cancer types	
Breast	89 (40.3%)
Colorectal	23 (10.4%)
Gastro-esophageal	20 (9.0%)
Lung	15 (6.8%)
Pancreatic and biliary tract	11 (5.0%)
Head and neck	11 (5.0%)
Hematologic	9 (4.1%)
Liver	8 (3.6%)
Urinary tract	7 (3.2%)
Gynecologic	6 (2.7%)
Kidney	4 (1.8%)
Thyroid	4 (1.8%)

Others including dual diagnosis	14 (6.3%)
Cancer stages (0 / I / II / III / IV / not confirmed)	7 / 40 / 53 / 40 / 37 / 44
Current treatments	
Chemotherapy	99 (44.8%)
Radiation therapy	69 (31.2%)
Hormone therapy	39 (17.6%)
No current treatment	48 (21.7%)
Surgical procedure within 3 months	47 (21.3%)
Have you experienced or been treated for depression, anxiety, or insomnia?	20 (9.0%)
Do you feel that you are currently depressed or anxious, or do you need help for your mood state?	49 (22.2%)
Symptoms assessments	
Stress and Anxiety to Viral Epidemic -6 (SAVE-6)	14.3 ± 4.4 (0 ~ 24)
Coronavirus Anxiety Scale (CAS)	1.2 ± 2.0 (0 ~ 11)
Work and Social Adjustment Scale (WSAS)	11.3 ± 8.9 (0 ~ 40)
Are you more afraid of coronavirus than cancer? (No:0 - Yes:10)	3.4 ± 3.3 (0 ~ 10)

Figure 1. The proportion of participants with SAVE-6, WSAS, and CAS

The proportion of participants with the SAVE-6 score ≥ 15 or WSAS score ≥ 11 (A); and SAVE-6 ≥ 15 or CAS score ≥ 5 (B)