



Depression, anxiety, stress and life satisfaction in patients with chronic spontaneous urticaria

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Abstract

Aim: Chronic spontaneous urticaria (CSU) is a skin disease with high rates of comorbid psychopathology. The aim of this study was to assess the relationship between CSU and anxiety, depression, stress and life satisfaction.

Materials and Methods: A total of 204 participants were included in the study, 101 of them were CSU patients and 103 of them were in the healthy control group. Demographic and clinical characteristics were obtained by the questionnaire created by our research team. Depression anxiety stress scale (DASS) and satisfaction with life scale were used to assess psychological status and life satisfaction. Statistical analysis was performed by using SPSS version 17.0.

Results: Stress and anxiety scores (15.88 ± 6.73 to 13.33 ± 6.05 , $p < 0.05$ and 10.06 ± 5.94 to 7.35 ± 5.09 , $p < 0.001$) were significantly higher in CSU patients than control group. Stress (16.8 ± 6.9 to 13.3 ± 5.4), anxiety (11.1 ± 5.8 to 7.4 ± 5.4) and depression (10.9 ± 6.3 to 7.0 ± 4.7) scores were significantly higher ($p < 0.05$), life satisfaction (22.3 ± 6.2 to 24.9 ± 4.7) scores were significantly lower ($p < 0.05$) in female patients with CSU. Unlike the control group, age and marital status did not make a significant difference on stress, anxiety, depression and life satisfaction in CSU patients.

Conclusion: Dermatological treatment alone is not sufficient in CSU. Patients with CSU also need psychological interventions to cope with stress, anxiety and depression, and thus increase their life satisfaction.



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Introduction

Chronic spontaneous urticaria (CSU) is a disease for at least 6 weeks and characterized by the development of swelling and sometimes angioedema without a specific cause [1]. Urticaria in the presence of identifiable physical or other provoking stimulus is defined as "inducible urticaria" [2]. Chronic urticaria (CU) is most common between the ages of 20-40 years, and it is seen twice as often in women as in men. It has been reported that two-thirds of CUs, almost 1% of the patients (0,5- 5%), have CSU and approximately one-third of them have physically inducible urticaria [3,4]. CSU is one of the skin diseases with the highest rates of comorbid psychopathology [5]. Despite significant gaps in understanding the pathogenesis, some findings suggest that psychosocial factors are likely to contribute to the development and exacerbation of CSU [6]. Psychological stress, depression and anxiety may play a role in the etiology of urticaria, especially in

triggering and exacerbation of acute attacks [7]. There is no curative treatment for CSU. For this reason, it is very important to determine the factors playing a role in the frequency and severity of CSU attacks. Exacerbation of CSU may be caused by psychological comorbidities or psychological problems may be experienced due to CSU itself [5,8]. Stress has an important role in the onset and/or exacerbation of the disease [9]. Physical and emotional fatigue and stress may increase both the lesions and the severity of itching in CSU. Some patients may benefit from psychological support for the treatment of CSU [10, 11]. Itching, pain, swelling, and physical appearance negatively affect life satisfaction and quality of life in CSU patients [12]. In some studies, it's reported that the stress level was higher in CSU patients [13,14]. CSU patients have more anxiety and depression symptoms [13, 15-17]. Life satisfaction decrease in those with anxiety disorders [18]. Most of the studies confirm that the quality of life and satisfaction of life are significantly decreased in CSU patients. This decrease is particularly evident in patients with depression and anxiety [19, 20]. The coexistence of CSU and

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psychosomatic diseases is known. Any psychiatric comorbidity in patients with CSU leads to a significant decrease in quality of life [21]. It has been reported that there is a positive significant relationship between life satisfaction and quality of life [22]. Considering the high positive correlation between CSU and poor psychological well-being, the burden of the disease can be alleviated with psychological interventions. The quality of life of CSU patients can be improved by relieving their depressive symptoms by intervening in anxiety-related personality traits and coping strategies [6]. The main purpose of this study was to evaluate whether patients with CSU have more stress, anxiety and depression compared to healthy control group. In addition, it was aimed to determine the effect of gender, age and marital status on this psychological comorbidities and life satisfaction in both groups.

Materials and Methods

Study population

The study population consisted of 101 patients with CSU and 103 healthy control participants.

Demographic characteristics

Demographic and social characteristics of the participants, co-morbidities, psychiatric help and/or drug therapy, duration and frequency of CSU, if any, were recorded.

Inclusion criteria

101 patients with CSU, admitted to dermatology outpatient clinic in our tertiary hospital between May 2021 and January 2022, were included in the study. In the same period, a healthy control group consisting of 103 people, who participated in the Google questionnaire on the internet and whose informed consent was obtained, was included in the study.

Exclusion criteria

Those with any dermatological disease other than CSU were not included in the study.

Study design

Case-controlled observational study.

Sampling method and sample size determination

Non-probability convenience sampling method was used. Sample size was adjusted on the basis of the minimum number of participants in which the study could be performed according to clinical relevance within acceptable error limits. All the participants met the confirmed case definition and completed questionnaire.

Ethical approval and informed consent

Permission of ethics committee/IRB has been taken for this study (Decision number and date: 59072, 16.04.2021). Informed consent was obtained from all the participants in this study.

Setting

Single centre tertiary hospital.

Primary outcomes

The main output measures of the study were the anxiety, depression, stress, and life satisfaction scores of both the study and control groups.

Measurement tools

For the outcome measurements, *Google questionnaire* and *7-point Likert scale for life satisfaction (LS)*, *depression anxiety stress scale (DASS)* were used.

Questionnaire and scales

Questionnaire

The questionnaire consisted of questions that determined the demographic and social characteristics of the participants. Also, It included some questions on health. The questionnaire was developed and conducted by our research team. *Questionnaire* announcement was made through social media.

Scales

LS scale

This is a scale that includes the general evaluation of one's own life and developed by Diener, Emmons, Larsen and Griffin [23]. The scale is five-item and 7-point Likert type.

DASS

This was developed by Lovibond and Lovibond [24]. The scale consists of 42 items and three subscales: stress, anxiety and depression. The measurement of each subscale consists of 14 items.

Data types and collection

Quantitative and qualitative data were obtained from questionnaire and scales. The data of the patients with CSU were collected in dermatology outpatient clinic. The data of the control group were collected online via internet due to the COVID-19 pandemic.

Statistical analysis

Descriptive statistics

We used to determine the numbers and percentages of the socio-demographic and clinical characteristics of the participants and the mean and standard deviations of each dependent variable. Pearson correlation coefficients analysis was performed to determine the relationships between each dependent variable.

Inferential statistics

The t-test was used to determine whether there was a difference between the CSU and control groups in terms of depression, anxiety and stress and life satisfaction scores. In addition, t-test and one-way analysis of variance were performed to determine whether there was a difference in the scale scores obtained from each dependent variable according to the gender, age, education and marital status of CSU patients and control group. Levene homogeneity test was performed to determine whether it showed normal distribution.

Table 1. Sociodemographic characteristics of the CSU patients and control groups.

Variables	Features	CSU patients group		Control group	
		N	%	N	%
Gender	Female	74	71.8	53	51.5
	Male	27	26.2	50	48.5
Age	18-29 (1)	25	24.8	35	34.0
	30-39 (2)	13	22.8	13	12.6
	40-49 (3)	16	15.8	16	15.5
	50-59 (4)	16	15.8	26	25.2
	60+ (5)	21	20.8	13	9.7
Educational Status	Primary school	33	32.7	-	-
	Middle school	15	14.9	2	1.9
	High school	12	11.9	15	14.6
	University	38	37.6	86	83.5
Marital status	Married	76	75.2	57	55.3
	Single	23	22.8	38	36.9
	Divorced	2	2.0	8	7.8
Living place	Town	28	27.7	25	24.2
	City	73	72.3	78	75.7
Chronic disease	+	28	27.7	29	28.2
	-	73	72.3	71	68.9
Psychiatric help	+	24	23.8	30	29.1
	-	76	75.3	73	70.9
Psychiatric medication	+	10	9.9	6	5.8
	-	90	89.1	97	34.2
Duration of urticaria	≤ 1 year	15	14.9		
	> 1 year	86	85.1		
Frequency of urticaria	Everyday	42	41.6		
	1 or more per week	28	27.7		
	1-2 times a month	31	30.7		

Statistical software and statistical significance

All the statistical analyses were performed by using SPSS program (SPSS Statistics for Windows, Version 17.0. Chicago: SPSS Inc.). p value of <0.05 was considered as statistically significant.

Results

Demographic characteristics of the participants

The demographic characteristics of the study and control groups are given in Table 1.

Table 2. Correlation and descriptive statistics between life satisfaction, stress, anxiety, and depression scores of CSU patients.

Variables	LS	Stress	Anxiety	Depression
LS	-			
Stress	-.282*	-		
Anxiety	-.297*	.682*	-	
Depression	-.466*	.705*	.700*	-
Mean score	22.8873	14.5931	8.7010	9.8627
Standart Deviation	5.54445	6.50927	5.68151	6.41203
Skewness	-.601	.387	.625	.616
Kurtosis	.109	.271	-.105	-.026
α	.83	.89	.89	.91

*p <0.05

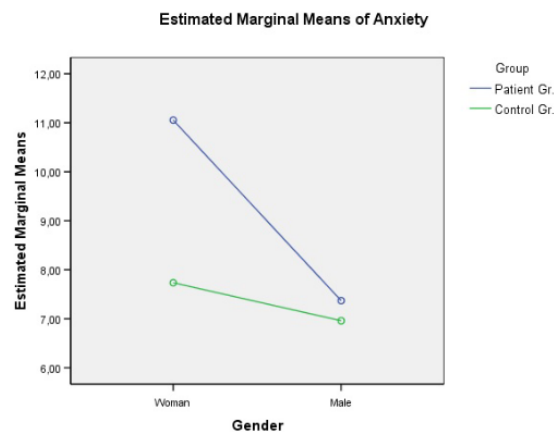
Reliability and validity of the scales

Cronbach's alpha coefficients were calculated to determine whether there were internal consistency of the measurement tools used for the data obtained in the current sam-

Table 3. T-test results regarding the differences in terms of life satisfaction, stress, anxiety and depression between CSU and control groups.

Variables	Group	N	\bar{x}	(sd)	t	p
LS	CSU patients	101	22.97	5.96	.211	.833
	Control	103	22.80	5.12		
Stress	CSU patients	101	15.88	6.73	2.847	.03*
	Control	103	13.33	6.05		
Anxiety	CSU patients	101	10.06	5.94	3.499	.001**
	Control	103	7.35	5.09		
Depression	CSU patients	101	9.92	6.19	.128	.898
	Control	103g	9.80	6.64		

*p value is a significant.



A: Anxiety

Figure 1. Diagrammatic representation of the differences in (A) anxiety, (B) depression, (C) stress and (D) life satisfaction according to gender in both groups.

Table 4. Life satisfaction, stress, anxiety and depression scores by gender variable and statistical differences.

Variables	Gender	CSU patients group				Control group			
		N	Mean ± SD.	t	p value	N	Mean ± SD.	t	p value
LS	Female	74	22.3 ± 6.2	-1.980	.050*	53	22.6 ± 4.8	-.410	.682
	Male	27	24.9 ± 4.7			50	23.0 ± 5.4		
Stress	Female	74	16.8 ± 6.9	2.421	.017*	53	13.7 ± 6.4	.666	.507
	Male	27	13.3 ± 5.4			50	12.9 ± 5.5		
Anxiety	Female	74	11.1 ± 5.8	2.852	.005*	53	7.7 ± 4.8	.771	.442
	Male	27	7.4 ± 5.4			50	6.9 ± 5.3		
Depression	Female	74	10.9 ± 6.3	2.931	.004*	53	10.6 ± 6.6	1.288	.201
	Male	27	7.0 ± 4.7			50	8.9 ± 6.5		

*p value is a significant.

Table 5. Statistical comparison of life satisfaction, stress, anxiety and depression scores according to age in CSU patients and control groups.

Variables	Age group	CSU patients group				Control group			
		N	Mean ± SD.	F	p value	N	Mean ± SD.	F	p value
LS	1.00	25	22.9 ± 5.8	.454	.769	35	21.1 ± 5.1	2.335	.061
	2.00	23	21.3 ± 5.5			13	22.3 ± 5.2		
	3.00	16	22.9 ± 5.9			16	25.3 ± 4.9		
	4.00	16	24.0 ± 6.1			26	23.6 ± 4.6		
	5.00	21	22.9 ± 5.9			10	23.4 ± 3.8		
	Total	101	17.1 ± 7.6			100	22.8 ± 5.1		
Stress	1.00	25	14.4 ± 6.1	1.122	.351	35	16.2 ± 6.1	3.799	.007*
	2.00	23	14.0 ± 5.3			13	13.3 ± 6.9		
	3.00	16	15.5 ± 5.5			16	11.3 ± 5.1		
	4.00	16	17.6 ± 7.7			26	11.2 ± 5.3		
	5.00	21	15.8 ± 6.7			10	11.7 ± 4.0		
	Total	101	9.7 ± 6.2			100	13.3 ± 6.0		
Anxiety	1.00	25	8.5 ± 5.6	2.097	.087	35	8.8 ± 5.6	1.530	.200
	2.00	23	8.6 ± 5.1			13	7.6 ± 4.3		
	3.00	16	10.1 ± 4.8			16	6.0 ± 4.5		
	4.00	16	13.1 ± 6.5			26	6.2 ± 4.6		
	5.00	21	10.0 ± 5.9			10	6.7 ± 3.2		
	Total	101	9.4 ± 7.3			100	7.3 ± 4.9		
Depression	1.00	25	10.0 ± 5.0	.087	.986	35	12.7 ± 7.0	3.348	.013*
	2.00	23	10.3 ± 5.7			13	8.8 ± 4.6		
	3.00	16	9.6 ± 4.8			16	7.8 ± 6.6		
	4.00	16	10.2 ± 7.4			26	7.9 ± 5.4		
	5.00	21	9.9 ± 6.1			10	8.2 ± 4.3		
	Total	101				100	9.7 ± 6.3		

Age group (1=[18,29], 2=[30-39], 3=[40-49], 4=[50-59], 5= \geq 59)

*p value is a significant.

One-way anova test was used for statistical analysis.

ple were found to have a good level of reliability.

- Reliability of scale of *The Satisfaction with Life Scale*

– Internal consistency of the scale

– Adjusted split-half time reliability of the scale Split-half value was 0.75 and Kuder Richardson-20 was 0.78.

- Validity scale of *The Satisfaction with Life Scale*

– Construct validity of the scale

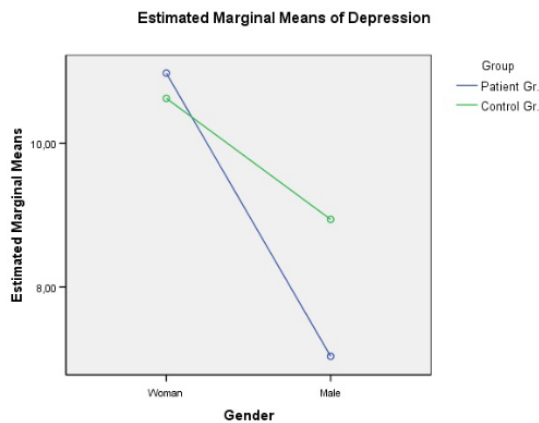
The Cronbach alpha coefficient of the scale was calculated with the data of this study was 0.83.

As a result of the confirmatory factor analysis for the construct validity of the scale, it was determined that the

Table 6. T-test results regarding the differences in life satisfaction, stress, anxiety and depression by marital status.

	Marital status	CSU patients group				Control group			
		N	Mean ± SD.	t	p	N	Mean ± SD.	t	p
LS	Married	76	23.3 ± 5.6	,693	.490	57	23.6 ± 4.8	2.245	.027*
	Single	25	22.3 ± 6.7			38	21.2 ± 5.6		
Stress	Married	76	15.8 ± 6.9	-,113	.910	57	11.4 ± 5.4	-4.086	.000*
	Single	25	16.0 ± 6.4			38	16.3 ± 6.1		
Anxiety	Married	76	10.2 ± 6.0	,738	.962	57	6.3 ± 4.5	-2.423	.017*
	Single	25	9.1 ± 5.8			38	8.9 ± 5.8		
Depression	Married	76	9.9 ± 5.8	,729	.468	57	7.8 ± 5.5	-3.884	.000*
	Single	25	8.9 ± 6.9			38	13.0 ± 7.4		

*p value is a significant.



B: Depression

Figure 2. Diagrammatic representation of the differences in (A) anxiety, (B) depression, (C) stress and (D) life satisfaction according to gender in both groups.

well-being of the scale was IFI = 0.999, TLI = 0.998, CFI = 0.999, SRMR = 0.020, RMSEA = 0.022. It was noted that there was a moderate ($r = -0.39$) negative correlation with the geriatric depression scale applied for the discriminant validity of the scale.

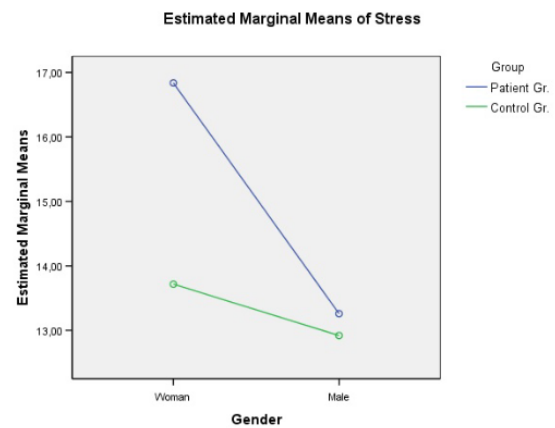
- Reliability of scale of *DASS*
 - Internal consistency of the scale

The Cronbach's alpha values for internal consistency reliability coefficients of *DASS-42* were found to be 0.92 for depression, 0.86 for anxiety and 0.88 for stress.

– Adjusted split-half time reliability of the scale
Guttman's split-half coefficient of the scale was 0.86.

- Validity scale of *DASS*
 - Construct validity of the scale

The construct validity of the Turkish form of the scale was examined with exploratory and confirmatory factor



C: Stress

Figure 3. Diagrammatic representation of the differences in (A) anxiety, (B) depression, (C) stress and (D) life satisfaction according to gender in both groups.

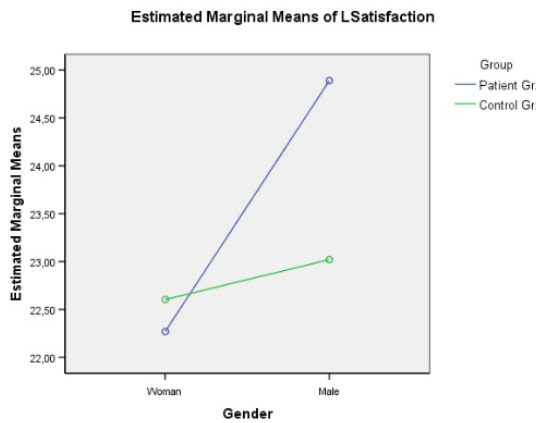
analysis. Analysis results were found as follows; IFI = 0.998, TLI = 0.996, CFI = 0.998, SRMR = 0.021, RMSEA = 0.021.

Results of correlation analysis between variables

Outcomes of correlations analysis related to the variables of this study are presented in Table-2. In addition, skewness and kurtosis values of each variable were calculated in order to determine whether the scores of life satisfaction, stress, anxiety and depression, which are dependent variables, showed normal distribution. As a result of the calculation, skewness and kurtosis values were found to be between .387 - .625 and -.026 - .271 respectively and were lower than the ± 1.0 value required for normal distribution (25). In other words, the kurtosis and skewness values of the variables were in the normal range.

Results of statistical analysis of the data

Table 3 shows the mean, standard deviation, and t values of the dependent variables between the patients with CSU and the control group. A significant difference was



D: Life satisfaction

Figure 4. Diagrammatic representation of the differences in (A) anxiety, (B) depression, (C) stress and (D) life satisfaction according to gender in both groups.

found between CSU patients and control group in terms of stress and anxiety ($p < 0.05$ and $p < 0.001$). There was no statistically significant difference between these groups in terms of life satisfaction and depression score. As a result of the t-test performed to determine whether there is a difference in life satisfaction, stress, anxiety and depression between male and female in both groups (Figure 1), a significant difference was found in all variables in CSU patient group (Table 4). While the mean life satisfaction scores of female were lower, the stress, anxiety and depression scores were higher than that of males. In contrast to these results, no significant difference was found between the genders in the control group among all variables. Table 5 shows the results of the comparison of life satisfaction, stress, anxiety, and depression scores for both groups according to age. There was a significant difference between stress and depression scores of the control group in terms of mean scores of the variables. Tukey test was performed for the source of the difference. According to the results, there was a significant difference ($F = 3.799$, $P < 0.05$) between the ages of 18-29 years and 40-49 years ($IJ = 4.944$, $P < 0.05$) and 50-59 years ($IJ = 4.987$, $p < 0.05$) in terms of the stress variable. In terms of depression scores, there was only a significant difference ($F = 3.348$, $P < 0.05$) between the ages of 18-29 and 50-59 years ($IJ = 4.791$, $P < 0.05$). According to these scores, the stress level of the youngest ones in the control group was high, while the stress level of the middle-aged individuals between the ages of 40 and 60 remained at the lowest level. Likewise, in terms of depression scores, the youngest group has the highest depression scores, while the lowest depression score was in the middle-aged group. However, no significant difference was found in control group in terms of life satisfaction ($F = 2.335$, $P > 0.05$) and anxiety ($F = 1.530$, $P > 0.05$) scores between the age groups. There was no significant difference in terms of any variable according to the age of individuals in CSU patient group. Table 6 shows the results of the comparison of life satisfaction, stress, anxiety, and depres-

sion scores for both groups according to marital status. There was no significant difference in terms of life satisfaction, stress, anxiety and depression in the CSU patient group according to the marital status, while a significant difference was found in the control group. Stress, anxiety and depression scores of singles in the control group were higher than those of married ones. The life satisfaction of married individuals was higher in both groups compared to singles. However, there was no significant difference between the variables according to marital status in terms of the mean scores of the individuals in the CSU patient group. There was no significant difference between the CSU patients and the control group in terms of education level, place of residence, whether they received psychiatric help and they used psychiatric drugs or not, and whether they had a chronic disease. In addition, there was also no significant difference between frequency and onset time of urticaria among the patients with CSU.

Discussion

In recent years, many studies have been conducted on whether CSU is a psychosomatic disease. A systematic review of 22 articles investigating the relationship between psychosocial factors and CSU shows that psychosocial factors are important in the development and exacerbation of CSU [6]. Engin et al. reported that one of the most affected areas of quality of life in CSU patients was psychological health [16]. In our study, stress scores were found higher in CSU patients compared to the control group. This result was consistent with some studies in the literature [13, 14]. Malhotra et al. reported that stressful life events had an important contribution in development and/or exacerbation of CSU [9]. As a matter of fact, 63% of the patients in our study answered positively to the question about whether they had experienced any stressful life events before showing CSU symptoms. Ben-Shoshan et al. reported in their meta-analysis that individuals suffering from CSU had higher levels of stress due to perceived events or real-life experiences [6]. CSU patients showed significantly higher anxiety symptoms in our study, which is consistent with the literature [8, 12, 13, 16, 21, 26-28]. But there was no significant difference between CSU patients and the control group in terms of life satisfaction and depression. This results are consistent with some studies in literature [21, 29]. Unlike our results, some studies reported that difference was found in terms of depression and life satisfaction in CSU patients compared to the control group [13, 16, 19, 20, 26, 30, 31]. As can be seen, the results regarding depression and life satisfaction in patients with CSU are still controversial in the literature. Gender is an important demographic factor in patients with CSU. The majority of CSU patients are female. Similar to the literature, approximately 72% of the patients with CSU were female in our study [2]. Also, there was a significant difference in terms of life satisfaction, stress, anxiety, and depression scores in female patients with CSU compared to males, while no significant difference was found among individuals in the control group in terms of these variables according to gender. This result revealed that stress, anxiety and depression symptoms were more common in female patients with CSU. Sibbald et al. have shown that female

patients with CSU had more stress and anxiety than males [32]. In the general population, it is reported that females have anxiety symptoms 2 times more than males [33]. In our study, a significant difference was found between depression scores in female patients with CSU compared to males. However, there are also studies in literature showing that there is no difference between females and males with CSU in terms of depression. Tat et al. reported that patients with chronic urticaria had higher depression and anxiety scores compared to the control group [28]. It is clear that stress, anxiety and depression cause deterioration in the quality of life. We found that life satisfaction in female patients with CSU was also significantly lower than that of males. Brzoza et al. have reported that women with CSU scored low on the quality of life "vitality" (energy and fatigue) subscale. Our results were consistent with these findings. [26]. There were significant differences in terms of stress and depression among different age groups in control group of our study. The lowest stress factor was observed in the individuals between the ages of 40 and 59, while the highest stress factor was observed in the young people between the ages of 18-29. We concluded that the young people were more affected by the stressors or their ability to cope with stress was lower. Likewise, in terms of depression, the youngest group had the highest scores, while the lowest score was in the middle-aged group (50-59 age group). However, there was no significant difference among the age groups of CSU patients. These results were similar to previous studies [15, 16, 21, 28, 34]. There was a significant difference between single and married people in the control group in terms of life satisfaction, stress, anxiety and depression, and no significant difference was found between marital status and any of these variables in CSU patients. Similar to our study, Barbosa et al. reported that there was not significant difference between marital status and these variables in CSU patients [35]. Although the stress, anxiety and depression scores of the patients with CSU were higher and the life satisfaction scores were lower than those of the control group. Even if the patients with CSU were married and in the middle age group, it was observed that marital status and age did not make a positive contribution to the protection of psychological health in CSU.

This study has some limitations. First of all, our study was conducted on a limited number of patients. Therefore, the results of our study may not be considered as a general or an accurate result. For this reason, further studies with a larger sample size need to be performed. All the volunteers were recruited via internet, which also may be considered as a limitation. Another limitation of this study is that the data were just based on self-report. Despite these limitations, the results are very important in many aspects in this study. First, patients with CSU have been shown to have higher levels of stress and anxiety. Therefore, this result is important in terms of showing the necessity of psychological help to cope with negative emotional problems. If CSU patients learn to control their stress and cope with their anxiety, the frequency of CSU attacks will decrease and worsening of the disease will be prevented. The second and other important result of this study was that there was a significant relationship between

female genders and stress, anxiety and depression. Moreover, female's life satisfaction was also lower than male. For this reason, we may consider that females with CSU are more vulnerable against this disease and CSU may become more complicated in female patients. Therefore, female patients need more coping methods to reduce stress, anxiety and depression symptoms to increase their life satisfaction compared to male patients. The third and other important result of our study was that young people experience much more stress in their lives. Therefore, in order to increase the success of CSU treatment, various coping methods should be used to reduce stress in young patients. All these results show that CSU patients need psychological interventions to cope with stress, reduce anxiety and depression and thus increase their satisfaction of life. It is also known that dermatological treatment alone is not sufficient for CSU patients. Curative medical treatment is currently not possible due to the complex nature of CSU. These situations also indicate that psychological interventions for CSU patients will increase their well-being and success of CSU treatment more.

Conclusion

The results of this study not only support the idea that personality traits and coping strategies are related to stress, anxiety and depression in CSU patients, but also emphasize the importance of psychological interventions in addition to traditional urticaria treatment in this patient group. As a result, it can be said that psychological interventions for CSU patients, in addition to traditional dermatological treatment, will contribute to the reduction of the frequency of CSU attacks and the severity of the disease. Thus, these psychological interventions will further reduce the burden of disease on both patients and the health system.

Competing interests

The authors declare that they have no competing interest.

Financial disclosure

The authors have no financial relationships relevant to this article to disclose.

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Ethical approval

This study was approved by the Ethics Committee of the University (Decision number and date: 59072, 16.04.2021).

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