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ORIGINAL PAPER

Determinants of distress levels in high-risk pregnant women – cross-sectional study

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ABSTRACT

Introduction and aim. Global and national care recommendations indicate that women with high-risk pregnancies should receive personalized and qualified care during this period. This study was conducted to determine the distress levels in high-risk pregnant women and affecting factors.

Material and methods. The cross-sectional this study was conducted with total of 416 high-risk pregnant women who met the inclusion criteria in the obstetrics clinic of a training and research hospital. The study data were collected with data collection form and "Tilburg Pregnancy Distress Scale (TPDS)."

Results. The mean TPDS total score of high-risk pregnant women was 18.25±6.85. It was found that planning pregnancy, gravida, and diagnosis of gestational hypertension, systemic diseases, and gestational diabetes in the present pregnancy was associated with pregnancy-specific distress ($p<0.05$; $\beta=0.291$, $\beta=0.158$, $\beta=0.272$, $\beta=0.137$, $\beta=0.116$, respectively).

Conclusion. It is advised that health professionals assess the distress levels of high-risk pregnant women and give personalized care during prenatal period.

Keywords. distress, health professional, high-risk pregnancy, nursing care

Introduction

A high-risk pregnancy is defined as a pre-pregnancy or current pregnancy-related condition that causes higher risk of maternal, fetal, or neonatal problems than normal during the antepartum, intrapartum, or postpartum period.[1] Although the diagnostic criteria vary, the literature has reported the prevalence of high-risk pregnancies from 6 to 33%.[2-4] The recent data in Türkiye indicate that 10–15% (130,000 per year) out of 1.3 million births include high-risk pregnancies.[5] Globally, three out of every four women die from perinatal causes such as severe hemorrhage, infection, preeclampsia and eclampsia, delivery complications, and unsafe abortion.[6] On the other hand, negative maternal-fetal outcomes such as caesarean delivery, intrauterine fetal death, neonatal intensive care follow-up, neonatal death, low birth weight, and stillbirth are reported in women with high-risk pregnancies.[4,7]

Psychological distress has also been reported besides the negative maternal-fetal outcomes in women with high-risk pregnancies.[8-11] Psychological distress is defined as a state of emotional suffering characterized by symptoms of depression and anxiety. In psychological distress, depression and anxiety symptoms co-occur with common somatic complaints and medically unex-

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plained syndromes.[12] However, the distinguishing characteristics of psychological distress include exposure to a stressful event that threatens physical or mental health, failure to cope with this stressor effectively, and emotional anguish resulting from this ineffectiveness.[13] The literature has documented more psychological distress experienced by women with high-risk pregnancies. Of pregnant women with congenital heart failure (CHF), 39% had traumatic distress, 22% had depression, and 31% had anxiety.[8] Yuksel et al. and Gözüyeşil and Arıöz Düzgün reported that the distress levels were high in pregnant women who were at risk in their current pregnancy.[9,14] A meta-analysis reported that 34% of pregnant women who were hospitalized due to obstetric complications had depression and 29% had anxiety, and compared to the general obstetric population, pregnant women who were followed up in the hospital due to their obstetric complications showed clinical symptoms of depression and anxiety two times more than the prevalence of depression and anxiety.[10] Some meta-analysis results also reported that the risk of developing depression was approximately 1.5 times higher in pregnant women who had pre-gestational diabetes or gestational diabetes compared the ones who did not.[11] Prenatal distress of women with high-risk pregnancies are reported to be affected by factors such as the level of education, perception of income-expenses, the education level of the spouse, the place where they lived for the longest period of childhood, wanting the pregnancy, and the number of children.[14] It is not certainly known whether the distress experienced in the prenatal period in women with high-risk pregnancies develops due to effects of some socio-demographic and obstetric variables of these women or only due to the current diagnosed risk.

Maternal distress experienced in the antenatal period causes low birth weight, intrauterine growth retardation (IUGR), preterm labor as well as cardiometabolic, respiratory and neurodevelopmental negative maternal-fetal-childhood health outcomes.[15] High-risk pregnancy threatens maternal-fetal health globally, and women with medical/obstetric risks are reported to have more mental health problems during pregnancy.[5,6,9-11]

It is known that the antenatal period increases the susceptibility to psychological health problems.[15] It is reported that pregnant women who are at risk during pregnancy are likely to experience mental health problems.[16-18] Although it is emphasized in studies that pregnancy complications can lead to physiological health risks up to maternal-fetal death, antenatal mental health problems are associated with the mother's postpartum mental health problems, and the negative cognitive and mental development of newborns in following life.[5,6,19-21] Global and national care recommendations indicate that women with high-risk pregnancies should receive personalized and qualified care during this period.[22,23] Although it is known that stressful situations such as high-risk pregnancy cause more psychological health problems, and their possible negative effects can be predicted within the framework of what is currently known, limited information is available on the distress in pregnancy among women with high-risk pregnancies.[5,6,8-10,14,19-21,24] Moreover, there seems to be a gap in the literature about which high-risk pregnancies have pregnancy-related distress levels and whether factors other than the current risk diagnosis during pregnancy have effects on pregnancy-specific distress. The current study is considered to have important scientific contributions that this study will contribute to filling an important gap in the literature and these results are believed to be useful for health authorities to make strategic plans and/or to create a road map to be used in practice.

Aim

This study was conducted to determine the distress levels in high-risk pregnant women and affecting factors.

Material and methods

Study design, sample size, and sampling strategy

This cross-sectional study was conducted in the perinatology clinics of a training and research hospital in Türkiye. Population of this study consisted of pregnant women hospitalized in obstetrics clinics with the diagnosis of high-risk pregnancy between March 2017 and March 2018. High risk factors identified for the decision to be admitted to the perinatology clinic; it includes hypertensive diseases, severe hyperemesis gravidarum, IUGR, polyhydramnios/oligohydramnios, diabetes mellitus, preterm/postterm labor, multiple pregnancy, Rh isoimmunization, systemic diseases (asthma, heart diseases, liver or kidney problems) and antenatal bleeding. Random sampling method was used in the study. Power analysis was performed to determine the sample size of the study. According to the study conducted by Bacacı in Türkiye, it was necessary to include at least 414 high-risk pregnant women, with a 5% difference at 90% power and 5% margin of error.[25] 457 pregnant women were invited to the study, and 41 pregnant women were not included in the study because they filled out the data collection forms incompletely. The study was completed with the participation of 416 pregnant women who met the inclusion criteria and agreed to participate in the study. The study included pregnant women who (1) were ≥18 years old, (2) were diagnosed with a high-risk pregnancy, (3) were ≥ in 12th gestational week, (4) were hospitalized for ≥3 days, (5) had a healthy fetus, and (6) were able to understand and answer the questions.

Instrument

The "Data Collection Form" and the "Tilburg Pregnancy Distress Scale (TPDS)" were used to collect data.

Data collection form

The form was prepared by the researchers in line with the relevant literature.[8,22,23,25-27] It included 19 questions about pregnant women's socio-demographic (age, education level, employment status, family type, etc.) and obstetric (gravida, gestational week, parity, current high-risk pregnancy diagnosis, etc.) features.

Tilburg pregnancy distress scale (TPDS)

TPDS was developed by Pop et al. in 2011 to diagnose pregnancy-specific distress.[28] Turkish validity and reliability of the scale was performed by Çapık and Pasinlioğlu in 2015.[29] The 16-item scale is responded on a 4-point Likert scale and included options ranging from "quite often" (0 points) and "never" (3 points). Items 3, 5, 6, 7, 9, 10, 11, 12, 13, 14, and 16 are scored reversely, and the total and subscale total scores are calculated. The subscales of the scale are "Negative Affect" and "Partner Involvement". Scores to be obtained from the scale range between 0 and 48 points, and the scores to be obtained from the negative affect and partner involvement subscales are 0-33 and 0-15 points, respectively. The scale has a cut-off point, and a total score of ≥28 indicates that pregnant women are at risk of experiencing distress. Cut-off points for partner involvement and negative affect subscale are ≥10 and ≥22, respectively. Cronbach's Alpha value was 0.83 in the original form of the scale,[29] while it was found 0.95 in the current study.

Data collection procedure

Each participant was given information about the study before the data collection forms were administered to the pregnant women, and data were gathered after their verbal and written consent was received. After the purpose, scope, ethical sensitivities and possible benefits of the study were explained to the pregnant women, the study process was started with the pregnant women who agreed to participate in the study and signed the informed consent form. The researchers obtained data from pregnant women through face-to-face interviews at the perinatology clinics of the training and research hospital where the study was carried out. Filling in the data collection tools was completed in approximately 10-15 minutes.

Ethical approval

The study was started after receiving ethics committee approval from the Non-Experimental Research Ethics Committee and written permission from the Provincial Health Directorate (decision no: 2017/61-35, date: February 10, 2017).

Data analysis

SPSS software was used to analyze the data (v. 24.0, IBM Corp., Armonk, NY, USA). Before the analysis was done, the Kolmogorov-Smirnov test was used to determine whether the data were distributed normally. Descriptive statistics are presented as a numbers (n), percentages (%), and mean and standard deviations (mean±SD). The independent sample t-test was used to compare two independent groups, the analysis of variance test (ANOVA) was used to compare three or more independent groups, and Tukey or Tamhane's T2 posthoc tests were used to determine which group indicated a statistical difference in those with ≥3 variables based on variance homogeneity. Multiple linear regression analysis (Stepwise model) was performed to determine the relationship between TPDS and the pregnant women's variables. A 95% confidence interval and a statistical significance of $p<0.05$ were used for all the findings.

Results

The majority of participating women with high-risk pregnancies (27.9%) were aged between 25 and 29, with a mean age of 28.96±6.06 years. It was found that 42.1% of the pregnant women were illiterate/primary school graduates, 91.6% were unemployed, and 78.4% had been married for ≥3 years.

Table 1. The distribution of the descriptive and obstetrics characteristics of the pregnant women and TPDS total mean scores according to descriptive and obstetrics characteristics (n=416)#

Characteristics	n	%	Mean±SD	Test and *p* (t/F)
Age groups (years) (mean±SD=28.96±6.06, min–max=18–44)				
≤ 24	109	26.2	17.66±7.44	
25–29	116	27.9	18.65±6.92	F=0.988
30–34	106	25.5	17.77±6.32	p=0.398
≥ 35	85	20.4	19.08±7.39	
Education status				
Illiterate/Primary school graduate	175	42.1	17.55±7.18	
Secondary school graduate	110	26.4	18.64±7.04	F=1.121
High school graduate	108	26	18.95±5.94	p=0.34
University graduate	23	5.5	18.52±7.18	
Employment status				
Employed	35	8.4	19.49±5.27	t=1.4
Unemployed	381	91.6	18.14±6.97	p=0.168
Spouse's education status				
Illiterate/Primary school graduate	145	34.9	17.90±7.25	
Secondary school graduate	102	24.5	18.76±6.5	F=0.322
High school graduate	129	31	18.29±6.58	p=0.809
University graduate	40	9.6	18.10±7.21	
Spouse's employment status				
Employed	408	98.1	18.28±6.77	t=0.523
Unemployed	8	1.9	17±10.69	p=0.601
Duration of marriage (years)				
1-2	90	21.6	17.62±6.93	t=-0.99
≥ 3	326	78.4	18.43±6.82	p=0.323
Family type				
Nuclear	342	82.2	18.4±6.72	t=0.952
Extended	74	17.8	17.57±7.39	p=0.342

Place of residence stayed longest				
Provincial center	305	73.3	18.33±6.91	F=0.24
County	88	21.2	18.24±6.74	p=0.787
Village or Town	23	5.5	17.30±6.57	
Perception of monthly income level				
Expenses less than income	214	51.4	18.26±7.07	
Expenses equal to income	183	44	18.15±6.75	F=0.185
Expenses more than income	19	4.6	19.16±5.26	p=0.831
Planning pregnancy				
Yes	319	76.7	17.24±6.49	t=-5.693
No	97	23.3	21.6±6.96	p<0.001
Gestational week (mean±SD=30.30±5.24, min-max=13-39)				
13-27 weeks	85	20.4	17.09±6.42	t=-1.756
≥28th week	331	79.6	18.55±6.93	p=0.08
Gravida				
1[a]	105	25.2	18.85±6.48	
2[b]	95	22.8	16.23±6.42	F=4.116
3[c]	89	21.5	18.21±6.91	p=0.007
≥ 4[d]	127	30.5	19.31±7.15	[a,b], [b,d]
Parity				
Nulliparty	139	33.4	18.34±6.36	
1	105	25.2	17.10±6.86	F=1.69
2	100	24.1	18.55±6.89	p=0.169
3	72	17.3	19.36±7.655	
Interpregnancy interval				
Primigravid	105	25.2	18.85±6.48	F=0.764
< 24 month	197	47.4	18.26±6.90	p=0.466
≥ 24 month	114	27.4	17.70±7.09	
Multiple gestation				
Yes	14	3.4	18.14±6.33	t=0.062
No (singleton pregnancy)	402	96.6	18.26±6.87	p=0.95
History of abortion				
Primigravid	105	25.2	18.85±6.48	F=0.623
Yes	120	28.9	17.52±6.91	p=0.537
No	191	45.9	18.85±6.48	F=0.623
History of stillbirth				
Primigravid	105	25.2	18.85±6.48	F=0.623
Yes	29	7.0	17.52±6.91	p=0.537
No	282	67.8	18.11±6.98	
History of high-risk pregnancy in previous pregnancies				
Primigravid[a]	105	25.2	18.85±6.48	F=3.975
Yes[b]	87	20.9	19.68±6.71	p=0.02
No[c]	224	53.9	17.42±6.97	[b,c]
High-risk pregnancy diagnosis in current pregnancy				
Risk of premature birth[a]	136	32.7	15.76±6.60	
Preeclampsia[b]	47	11.3	17.57±5.39	
Gestational diabetes[c]	42	10.1	19.26±6.77	F=7.715
Gestational hypertension[d]	64	15.4	21.78±6.57	p<0.001
Systemic diseases[e]*	57	13.7	20.42±6.53	[a,c], [a,d]
Placenta previa[f]	21	5.0	18.24±6.84	[a,e]
Premature rupture of membrane[g]	49	11.8	17.84±6.96	

[#] SD – standard deviation, TPDS – Tilburg Pregnancy Distress Scale, F – One-way ANOVA test, t – Independent sample t-test, * – systemic diseases: heart disease, kidney disease, liver disease, and asthma; all pregnant women have gone antenatal care visit; the letters a, b, c, d, e, f and g indicate the group that makes the difference

The majority of the pregnant women's spouses (34.9%) were illiterate/primary school graduates, and almost all of them were working (98.1%). Besides, 82.2% had a nuclear family, 73.3% resided in the provincial center, more than half (51.4%) had income less than expenses, and 23.3% reportedly did not plan their pregnancy. The mean gestational week was 30.30±5.24 weeks, 20.4% of them were in the 2nd trimester (13–27 weeks), and 79.6% of them were in the 3rd trimester (≥28th weeks). It was found that 25.2% of the pregnant women had their first pregnancy, 33.4% never gave birth, the period between the previous pregnancy and the current pregnancy was <24 months for 47.4%, and almost all of them (96.6%) had singleton pregnancies. It was also found that 28.9% of pregnant women had abortions, 7% had a history of stillbirth, and 20.9% had a history of high-risk pregnancy in previous pregnancies. Clinical diagnoses showed that 32.7% had a risk of premature birth, 11.3% had preeclampsia, 10.1% had gestational diabetes, 15.4% had gestational hypertension, 13.7% had systemic diseases (heart disease, kidney disease, liver disease, and asthma), 5.0% had placenta previa, and 11.8% had premature rupture of membranes. The total TPDS score averages indicated no statistically significant differences according to age of women with high-risk pregnancies and the age of their spouses, education level and employment, marriage duration, family type, place of residence stayed longest, perception of monthly income level, gestational week, parity, interpregnancy interval, multiple gestations, and history of stillbirth (p>0.05). A statistically significant difference was found between the TPDS total mean score and planning of pregnancy, gravida, history of abortion, and high-risk pregnancy in the previous pregnancy (p<0.05). The mean TPDS total mean scores of pregnant women with gestational diabetes, gestational hypertension, and systemic diseases indicated a statistically significant difference (p<0.05) (Table 1).

Table 2. The mean scores of TPDS scale and subscales of the pregnant women (n=416)*

TPDS total and subscales	Min-Max	Mean±SD
Negative affect subscale	0–28	13.13±5.67
Partner involvement subscale	0–15	5.12±2.93
Total	1–36	18.25±6.85

* SD – standard deviation, TPDS – Tilburg Pregnancy Distress Scale

Participating women's negative effect and partner involvement subscales and the TPDS total mean scores were found 13.13±5.67, 5.12±2.93, and 18.25±6.85, respectively (Table 2).

Table 3 shows the results of a multiple linear regression analysis of the variables associated with TPDS total mean scores of women with high-risk pregnancies. Anal-

ysis results showed that the effect of being diagnosed with a high-risk pregnancy in the presence of participating women's all existing variables, planning pregnancy, gravida, gestational hypertension in the current pregnancy, systemic diseases, and gestational diabetes indicated a statistically significant difference (p<0.001). The TPDS total mean scores of those who did not plan their pregnancy compared to those who did were approximately 5 points (p<0.001) higher, mean scores of those with primigravida were 2.5 points (p=0.001) higher compared to those with second pregnancy, and compared to those at risk of premature birth in their current pregnancy, the mean scores of those with gestational hypertension were 5 points (p<0.001) higher, mean scores of those with systemic diseases were 3 points (p=0.004) higher, and mean scores of those with gestational diabetes were 3 points (p=0.013) higher.

Table 3. Multiple linear regression analysis results for TPDS total scores (n=416)#

Variables	B	SE	β	t	p	%95 CI for β	
						Lower Bound	Upper Bound
Constant	10.388	1.075	–	9.661	<0.001	8.274	12.502
Planning pregnancy *No vs. Yes*	4.710	0.770	0.291	6.118	<0.001	3.197	6.224
Gravida *Primigravid vs. 2. pregnancy*	2.483	0.48	0.158	3.319	0.001	1.012	3.954
High-risk pregnancy diagnosis in current pregnancy							
Gestational hypertension vs. The risk of premature birth	5.152	0.882	0.272	5.839	<0.001	3.417	6.887
Systemic diseases vs. The risk of premature birth	2.721	0.934	0.137	2.911	0.004	0.884	4.557
Gestational diabetes vs. The risk of premature birth	2.634	1.053	0.116	2.501	0.013	0.564	4.705

#TPDS – Tilburg Pregnancy Distress Scale, B – unstandardized regression coefficient, SE – standard error, β – standardized, t – independent sample t-test value, 95% CI – 95% confidence interval, n=416, R=0.411, R^2=0.169, Adjusted R^2=0.159, F=16.668, and p<0.001, * – systemic diseases: heart disease, kidney disease, liver disease, and asthma; stepwise model was used

Discussion

Several negative maternal-fetal outcomes can be documented in high-risk pregnancies during the antenatal, innatal, and postnatal periods.[4,7] The pregnancy process itself could cause women to experience psychological changes.[15] Pregnant women who are at risk during pregnancy are reported to experience a variety of mental health problems.[9,14,24,25] The mean TPDS total, negative affect, and partner involvement subscale scores of pregnant women with high-risk pregnancies were found to be 18.25±6.85, 13.13±5.67, and 5.12±2.93, respectively, in the current study. A study conducted with women with high-risk pregnancies reported the mean TPDS total, negative affect, and partner involvement subscales scores as 29.05±11.6, 23.17±9.8, and 5.88±4.8, respectively, and their pregnancy-related distress levels were higher than the ones reported in this study.[14] In a study, the rate of maternal psychiatric symptoms was found 48.5% in high-risk pregnant women.[18] The study conducted by Woods et al. reported that 18.9% of pregnant women with ≥2 chronic diseases and 32.3% of women with complications experienced high levels of stress; they were found to have experienced psychological stress during pregnancy approximately 3 times [OR=3.1, 95% CI=1.8–5.5] and 1 time [OR=1.2, 95% CI=0.72–1] more, respectively.[25] In two studies conducted, prenatal distress levels were found to be higher in pregnant women with high-risk/problems with their current pregnancy.[9,24] According to a meta-analysis, pregnant women who were followed up in the hospital due to obstetric problems had two times more anxiety and depression symptoms than the general obstetric population, and around three out of every ten pregnant women had depression and anxiety (34% and 29%, respectively).[10] Studies reports that pregnant women with pregnancy complications experience various mental health problems, ranging from stress to depression, and have psychiatric symptoms. The current study has revealed that high-risk pregnant women have psychological distress, and have presented that risky pregnant women experience negative affect and that partner involvement is important for these pregnant women.

Women who have high-risk/current pregnancy-related problems are reported to experience more prenatal distress than those who do not.[14,30] Furthermore, various socio-demographic and obstetric variables that may represent a risk associated with pregnancy have been associated with prenatal distress.[14] In addition to the risk in the currently diagnosed pregnancy, factors such as education level, perception of income-expenses, spouse's education level, place of residence for the longest period of childhood, wanting the pregnancy, and the number of children could have effects on pregnancy distress.[14] This study found that unplanned pregnancy, primigravida and three or more pregnancies, gestational diabetes mellitus, gestational hypertension and systemic disease increase the distress level of high-risk pregnant women. Regression analysis presented that the most important determinants of distress levels in high-risk pregnant women were unplanned pregnancy, primigravida, hypertension during pregnancy, systemic disease and gestational diabetes mellitus. The study conducted by Gözüyeşil and Arıöz Düzgün detected that the difference between wanting the pregnancy and the TPDS total mean scores was statistically significant (p<0.05). A study determined that approximately 4 (39%) in every 10 pregnant women with

CHF experienced traumatic distress, 3 (31%) experienced anxiety and 2 (22%) experienced depression.[8] According to the study conducted by Lee et al., the risk of depression in pregnant women who had pregestational or gestational diabetes is approximately 1.5 times greater [RR=1.430, 95% CI=1.251–1.636] than in those who did not.[11] Our findings show that, in addition to the association between pregnancy distress and gestational hypertension, systemic diseases and gestational diabetes, unplanned pregnancy and high-risk pregnancy in the second pregnancy are effective in pregnancy-specific distress in women. Our research result is consistent with previous studies reporting that various obstetric factors have an impact on the mental health of high-risk pregnant women. It also points out that hypertension, diabetes and systemic complications during pregnancy may be important health risks that increase the distress levels of high-risk pregnant women. On the other hand, it suggests that the importance of pregnancy planning for the mental health of high-risk pregnant women is noteworthy and that those experiencing their first pregnancy may be more prone to maternal psychological health risks.

Study limitations

This study has some limitations. It was conducted in a single center in Türkiye the results can therefore be generalized only to pregnant women living in that province and having similar characteristic features. Secondly, limitation is due to the self-reporting of the levels of psychological distress which may not always be aligned with objective assessment by health professionals. The restrictions also include that the study was conducted only on a sample of high-risk women with pregnancy – without a control sample (women with physiological pregnancy).

Implications for health care practice

Women who are followed up in the hospital due to high-risk pregnancies during the prenatal period should be provided with optimal care to preserve and improve maternal, fetal, and neonatal health. We consider that provision of care by health professionals for the mental health needs of high-risk pregnant women in line with their risk diagnosis may increases maternal well-being. It is recommended to evaluate the pregnancy-related distress in the women with high-risk pregnancies and to manage the care process in cooperation with psychiatry/psychological counselling clinics when deemed necessary.

Conclusion

The current study detected that women with high-risk pregnancies experienced pregnancy-related distress. It has been found that pregnant women of almost all ages experience psychological distress, regardless of their education level, employment status, spouse's education level and employment status, duration of marriage, family type, place of residence for the longest time, and income level. Obstetric factors such as gestational age, parity, interval between the last two pregnancies, multiple pregnancy, abortus and stillbirth history have been detected to be ineffective on the distress levels of high-risk pregnant women. It has been determined that unplanned pregnancy, high-risk pregnancy history in the previous pregnancy, gestational hypertension, systemic diseases and gestational diabetes are factors that increase the distress of high-risk pregnant women of all ages. Moreover, when all known sociodemographic and obstetric variables were taken into account, it was concluded that the most important determinants of the distress levels of high-risk pregnant women were unplanned pregnancy, primigravida, gestational hypertension, gestational diabetes mellitus and systemic disease.

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Declarations

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Author contributions

Conceptualization, P.K. and E.N.; Methodology, P.K. and E.N.; Formal Analysis, P.K. and E.N.; Data Curation, P.K. and Z.Ç.; Writing – Original Draft Preparation, P.K.; Writing – Review& Editing, P.K. and E.N.; Supervision, E.N.

Conflicts of interest

No potential conflict of interest was reported by the authors.

Data availability

The data sets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethics approval

The study was started after receiving ethics committee approval from the Non-Experimental Research Ethics Committee and written permission from the Provincial Health Directorate (decision no: 2017/61-35, date: February 10, 2017).

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