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# ORIGINAL INVESTIGATION

# Evaluation of the relationship between the STOP-Bang score with oxygen reserve index and difficult airway: a prospective observational study



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### **KEYWORDS**

Airway management; General anesthesia; Hypoxia; Obstructive sleep apnea; Oxygen reserve index

#### Abstract

*Background*: Patients diagnosed with Obstructive Sleep Apnea (OSA) syndrome have a tendency towards hypoventilation, hypoxia, and hypercarbia in the perioperative period. This study hypothesized that the Oxygen Reserve Index (ORi) could predict possible hypoxia and determine difficult airways in patients at risk for OSA, as determined by the STOP-Bang questionnaire.

*Methods:* This prospective study included adult patients undergoing elective surgery under general anesthesia with endotracheal intubation, divided into two groups: low risk (0-2 points) and high risk (3-8 points) based on their STOP-Bang questionnaire results. The primary outcome measure was the highest ORi value reached during preoxygenation and the time to reach this value. Data were recorded at four time points: before preoxygenation (T1), end of preoxygenation (T2), end of mask ventilation (T3), and end of intubation (T4), as well as partial oxygen pressure values in T1, T2, and T4. The secondary outcome measures were the grading scale for mask ventilation, Cormack-Lehane score, tonsil dimensions, use of a stylet, and application of the burp maneuver during intubation.

*Results*: In the high-risk group, preoperative peripheral oxygen saturation values, the highest ORi value reached in preoxygenation, and ORi values at T3 and T4 times were lower, and the time to reach the highest ORi value was longer (p < 0.05).

*Conclusion:* Using ORi in patients with OSA may be useful in evaluating oxygenation, and since difficult airway is more common, ORi monitoring will better manage possible hypoxic conditions. © 2023 Sociedade Brasileira de Anestesiologia. Published by Elsevier España, S.L.U. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

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Introduction

Obstructive sleep apnea (OSA) syndrome is characterized by recurrent episodes of upper airway obstruction during sleep,

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accompanied by sleep fragmentation, hypoxemia, and arterial oxygen desaturation. Although OSA patients tend to be obese, non-obese patients can also have OSA. In obese patients, increased adipose tissue in the neck predisposes to airway narrowing, while in patients with normal body weight, tonsillar hypertrophy or craniofacial skeletal abnormalities predispose to narrowing or closure of the airway.<sup>1</sup> Since most patients are not diagnosed with OSA in the preoperative period, any patient undergoing elective surgery may present with OSA symptoms or signs.<sup>2</sup> Recognizing these patients prevents complications that may develop in the perioperative process or early intervention. The increased frequency of difficult mask ventilation and difficult intubation in patients with OSA makes preoperative evaluation and appropriate preparation crucial.<sup>3</sup>

Several questionnaires have been developed for diagnosing OSA syndrome. These questionnaires screen patients at risk for OSA and direct them toward polysomnography, which provides a definitive diagnosis. The STOP-Bang questionnaire is preferred due to its ease of application, speed, and practicality. Studies comparing the questionnaire with polysomnographic tests have shown high sensitivity, especially in highrisk groups.<sup>4,5</sup>

The Oxygen Reserve Index ( $ORi^{TM}$ ) is a noninvasive and continuous measurement parameter used to assess realtime oxygen reserve status at a Partial pressure of Oxygen ( $PaO_2$ ) in the mild hyperoxia range of approximately 100 -200 mmHg. ORi is measured by applying a sensor to the finger and varies in the range of 0.00–1.00, depending on the oxygenation reserve status.<sup>6</sup> Additionally, ORi allows clinicians to accurately assess the patient's oxygenation status without arterial blood gas administration, preventing unnecessary and unexpected hypoxia.<sup>7</sup>

Based on these findings, this study hypothesizes that ORi can be used to predict possible hypoxia and determine difficult airways in patients at risk for OSA, as determined by the STOP-Bang questionnaire.

# Methods

# Ethical approval

This prospective observational study was conducted at Zonguldak Bülent Ecevit University Health Training and Research Center, Zonguldak, from January 2021 to June 2022 after obtaining approval from the faculty ethics committee (ethical approval No. 2020-22/16) and written consent from the patients. The principles of the Declaration of Helsinki and the STROBE (Strengthening of Reporting of Observational Studies in Epidemiology) guidelines were followed when reporting this study. This study was registered at Clinicaltrials.gov (NCT05640856).

#### Participants

The study included 72 patients aged 18–65 in the American Society of Anesthesiologists (ASA) I–III risk group intubated under general anesthesia and undergoing elective surgery. Patients previously diagnosed with OSA syndrome before preoperative evaluation, as well as those diagnosed with asthma, chronic obstructive pulmonary disease, heart failure or coronary artery disease, morbid obesity (Body Mass Index –  $BMI > 45 \text{ kg}.\text{m}^{-2}$ ), alcohol or drug addiction, pregnant or lactating women, and those allergic to the drugs to be administered, were excluded from the study.

#### Procedures and patient management

The patients in the study were divided into two groups: Group L, low risk (0–2 points), and Group H, high risk (3–8 points), according to their STOP-Bang score. Patients were monitored using electrocardiography and noninvasive blood pressure as they were taken to the operating room. A Rainbow<sup>®</sup> Sensor (Masimo Corp., Irvine, CA, USA) was applied to the fourth finger on the arm without a blood pressure cuff and covered with a light shielding sheath to measure ORi and Peripheral Oxygen Saturation (SpO<sub>2</sub>). This sensor was imaged using Root<sup>®</sup> with the Radical-7<sup>®</sup> instrument (Masimo Corp.). A bilateral cerebral oximetry (NIRS) sensor was also attached to the patient's forehead.

In patients who were not premedicated, a 20G arterial cannula was inserted in the arm to which the ORi probe was not attached, and preoperative blood gas was measured at the bedside. Patients were then informed about preoxygenation, and it was applied for 3 min with 6 L.  $\min^{-1}$  100% oxygen using a properly fitted mask without leakage.

Patients who could not cooperate with preoxygenation and whose expiratory oxygen concentration (FeO<sub>2</sub>) did not exceed 80% were excluded from the study. After 3 min, anesthesia was induced using 1 mg.kg<sup>-1</sup> lidocaine, 2–2.5 mg.  $kg^{-1}$  propofol, and 1 mcg. $kg^{-1}$  fentanyl. Mask ventilation was graded using the Han scale<sup>8</sup> (Grade 1: Ventilated by mask, Grade 2: Ventilated by mask with oral airway, Grade 3: Difficult to ventilate (insufficient, unstable, requiring two assistants, significant gas leakage despite appropriate mask etc.), Grade 4: Unable to ventilate (with/without neuromuscular blockade). A mask grade > 2 was defined as difficult mask ventilation. Mask ventilation was continued for 120 seconds after administration of 0.6 mg.kg<sup>-1</sup> rocuronium, and at the end of this period (T3), Endotracheal Intubation (ETI) was performed (T4). The same blinded physician performed mask ventilation and intubation. Tonsil size was evaluated according to the Brodsky<sup>9</sup> scale, classifed as; grade 0 Tonsils within the tonsillar fossa; Grade 1 Tonsils just outside of the tonsillar fossa and occupy  $\leq 25\%$  of the oropharyngeal width; Grade 2 Tonsils occupy 26-50% of the oropharyngeal width; Grade 3 Tonsils occupy 51-75% of the oropharyngeal width; Grade 4 Tonsils occupy > 75% of the oropharyngeal width and the patient's Cormack-Lehane (CML) score was assessed during laryngoscopy. The time from the beginning of the laryngoscopy to the insertion of the endotracheal tube between the vocal cords was noted as the apnea time. Arterial blood gas samples were taken simultaneously with intubation. The standard difficult intubation protocol was applied to all patients in the study. After the first intubation attempt, in cases where the vocal cords could not be seen with laryngoscopy (CML score III and IV), intubation was attempted using the stylet and/or burp maneuver (second attempt). Intubation was considered difficult when a video laryngoscope was required.

#### Data collection and outcome measures

Age, gender, body mass index, ASA score, and smoking history were determined before surgery, along with the STOP-Bang score. Before preoxygenation (T1), at the end of preoxygenation (T2), during mask ventilation (T3), and at intubation (T4), hemodynamic parameters, ORi and NIRS values were recorded for all patients. PaO<sub>2</sub> values were examined and recorded at T1, T3, and T4. The highest ORi value (maximum ORi) and the time to reach this value (time to reach maximum ORi) were recorded. To examine the relationship between ORi and PaO<sub>2</sub>, the difference between T1 and T2 ORi values was recorded as ORi change 1 ( $\Delta$ ORi 1), the difference between T2 and T4 ORi values was recorded as ORi change 2 ( $\Delta$ ORi 2), the difference between T1 and T2 PaO<sub>2</sub> values was recorded as  $PaO_2$  change 1 ( $\Delta PaO_2$  1), and the difference between T2 and T4 PaO<sub>2</sub> values was recorded as PaO<sub>2</sub> change 2  $(\Delta PaO_2 2)$ . Secondary endpoints included the need for stylet use, burp maneuver, video larvngoscope for intubation success, and the grade of mask ventilation.

#### Sample size calculation

The sample size was determined based on the ORi values at the end of preoxygenation, with a 95% confidence level  $(1-\alpha)$ , 95% test power  $(1-\beta)$ , and d = 0.826 effect size, requiring a total minimum of 66 patients.<sup>10</sup> Considering a potential 15% loss in follow-up, 76 patients were included in the study.

#### Statistical analyses

The data were analyzed using IBM SPSS 22. The normal distribution test was conducted using the Kolmogorov-Smirnov test. Normally distributed data were evaluated using parametric tests, while non-normally distributed data were evaluated using non-parametric tests. The analyses used the Mann-Whitney U, t-test, Chi-Square, Friedman, and Spearman correlation analyses. A p-value less than 0.05 was considered statistically significant.

# Results

# Demographic and clinical characteristics of participants

Out of the 76 patients assessed for eligibility, 72 were included in the study (Fig. 1). The mean age of the patients included in the study was  $44.40 \pm 10.98$  years (range: 18 -65 years). The demographic and clinical characteristics of the two groups are presented in Table 1. There were no significant differences between the groups regarding age, gender, and smoking status. However, Group H had higher numbers of ASA III patients and higher BMI values than Group L, whereas Group L had more ASA I patients.

No significant differences in heart rate and mean arterial pressure were observed between the two groups. However, the SpO<sub>2</sub> values in Group H were significantly lower at T1 (p = 0.009). In addition, ORi values were significantly lower in Group H at T3 and T4. It was also determined that both

groups had a significant difference in ORi measurements for all four time periods (Table 2).

There were no significant differences in PaO<sub>2</sub> values between the two groups. However, there was a significant difference in the measurements for all periods within both groups (Table 3). The two groups had a statistically significant difference regarding maximum ORi, ORi change during apnea, and  $\Delta$ PaO<sub>2</sub> 1 measurement. Maximum ORi and  $\Delta$ PaO<sub>2</sub> 1 measurements were lower in Group H, while ORi change during apnea duration was greater in Group H (Table 4).

There was no statistically significant difference between the two groups in terms of the Mallampati classification and the Cormack-Lehane classification. However, tonsil size was 25-50% larger in Group H than in Group L (p = 0.027). Difficult mask ventilation, BURP maneuver, and stylet use were significantly higher in patients with a high risk of OSA (Table 5).

Values are presented as mean  $\pm$  standard deviation or number (%). MV: Mask ventilation, VL: Videolaryngoscope.

When examining the correlations between change in PaO<sub>2</sub> and ORi, a weak positive correlation was found between  $\Delta$ ORi 1 and  $\Delta$ PaO<sub>2</sub> 1 (p = 0.003, r = 0.343), as well as a weak positive correlation between  $\Delta$ ORi 2 and  $\Delta$ PaO<sub>2</sub> 2 (p = 0.001, r = 0.392).

#### Discussion

In all patients, regardless of their risk of OSA determined by the STOP-Bang score, ORi values ranged from 0 to 1, and  $PaO_2$  did not fall below 60 mmHg. Preoperative oxygen saturation was lower in the high-risk group, but there was no significant difference in ORi and  $PaO_2$  between the low and high-risk groups. The high-risk group had the lower highest ORi value during preoxygenation, while the ORi and  $PaO_2$  changes tended to increase more in the low-risk group.

Difficult mask ventilation was more frequent in patients with a high STOP-Bang score. The tonsil size was larger in the high-risk group, and the need for stylet use and Burp maneuvers during intubation were higher. There was a weak positive correlation between the change in ORi and  $PaO_2$  before, after preoxygenation, and after intubation.

Early detection of desaturation is crucial for patient safety. Measurement of the oxygen reserve index provides a non-invasive way to monitor real-time oxygenation status in the mildly hyperoxic range (100 mmHg <  $PaO_2 \leq 200 \text{ mmHg}$ ).<sup>7</sup> The oxygen reserve index has been used to detect desaturation in various clinical scenarios, including pediatric intubation and airway surgeries, rapid sequence induction and intubation, and one-lung ventilation.<sup>11-13</sup> In our study, the ORi values of patients ranged from 0 to 1, and there was no decrease in peripheral oxygen saturation. We believe this is due to the low number of high-risk patients with a STOP-Bang score of 6 or higher in the study.

In a previous study comparing SpO<sub>2</sub>, ORi, and PaO<sub>2</sub> measurements during general anesthesia induction, ORi showed hypoxia before the decrease in saturation, and ORi and PaO<sub>2</sub> measurements were correlated in the moderately hyperoxic range but weakly correlated in the case of high hyperoxia where PaO<sub>2</sub> exceeds 240 mmHg.<sup>14</sup>



Figure 1 Flowchart of patients' enrolment, allocation, and analysis procedure.

Table 1 Comparison of demographic and clinical characteristics of the group	Table 1	Comparison of	demographic and	clinical characteristics o	f the groups.
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	Group L (n = 35)	Group H (n = 37)	p
Gender Female/Male	17/18 (48.6/51.4)	20/17 (54.1/45.9)	0.819
Age, years	$\textbf{41.97} \pm \textbf{10.77}$	$\textbf{46.70} \pm \textbf{10.8}$	0.068
ASA physical status, I/II/III	8/26/1 (22.9/74.3/2.9)	0/23/14 (0/62.2/37.8)	<0.001
Body mass index, kg.m <sup>-2</sup>	$\textbf{29.55} \pm \textbf{5.93}$	$\textbf{39.21} \pm \textbf{5.66}$	<0.001
Smoking status +/-	15 /20 (42.9/57.1)	12 /25 (32.4/67.6)	0.361

Values are presented as mean  $\pm$  standard deviation or number (%). ASA, American Society of Anesthesiologists.

Table 2	Comparison	of ORi values	between groups.
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	Grup L (n = 35)	Grup H (n = 37)	pa
T1	0.006 ± 0.02 (0-0.09)	0 (0–0)	0.071
Т2	$0.79 \pm 0.21$ (0.33–1)	$0.72 \pm 0.24$ (0.09–1)	0.193
Т3	$0.56 \pm 0.22$ (0.15–0.92)	$0.42 \pm 0.21$ (0.05–0.86)	0.038
T4	$0.52 \pm 0.2$ (0.13–0.91)	$0.38 \pm 0.21$ (0–0.85)	0.030
p <sup>b</sup>	<0.001	<0.001	

Values are presented as mean  $\pm$  standard deviation or Minimum-Maximum.

<sup>a</sup> *p*-value, comparison between groups.

<sup>b</sup> p-value, compared within the group.

T1, Before preoxygenation; T2, After preoxygenation; T3, End of mask ventilation; T4, After intubation.

This study found a positive, weak correlation between ORi and  $PaO_2$  changes during preoxygenation and after intubation. This may be due to the high degree of hyperoxia achieved after 3 min of preoxygenation with 100% oxygen. Although patients had difficult intubation in both groups, no hypoxemia was observed in blood gases taken after intubation. Further studies with lower  $FiO_2$  or shorter duration preoxygenation methods are needed in

Table 3	Comparison of arteria	Il Partial Pressure of Oxygen	(PaO <sub>2</sub> ) values between groups
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	Group L (n = 35)	Group H (n = 37)	p <sup>a</sup>
T1	$91.49 \pm 12.21$ (91)	87.97 ± 15.48 (85)	0.102
Т2	$410.97 \pm 72.97$ (427)	$380.70 \pm 81.46$ (395)	0.098
T4	$330 \pm 70.53~(321)$	$315.41 \pm 86.92$ (307)	0.333
р <sup>ь</sup>	<0.001	<0.001	

Values are presented as mean  $\pm$  standard deviation.

<sup>a</sup> *p*-value, comparison between groups.

<sup>b</sup> *p*-value, compared within the group.

T1, Before preoxygenation; T2, After preoxygenation; T3, End of mask ventilation; T4, After intubation.

Table 4	Comparison of maximum ORi, time to reach maximum ORi, apnea time, ORi change in apnea time, $\Delta$ ORi and $\Delta$ PaO $_2$ val-
ues betwe	n groups.

	Group L (n = 35)	Group H (n = 37)	р
Max. ORi	0.86 ± 0.18 (0.94)	0.79 ± 0.21 (0.87)	0.037
Time to reach max. ORi	$101.26 \pm 36.62$ (90)	115.57 $\pm$ 41.79 (119)	0.159
Apnea time (sec)	$34.25 \pm 18.70$ (29)	$38.59 \pm 19.84$ (32)	0.199
ORi change during apnea	$0.04 \pm 0.08 \; (0.02)$	$0.06 \pm 0.11 \ (0.03)$	0.039
ΔORİ 1	$0.79 \pm 0.22$ (0.85)	$0.72 \pm 0.24 \ (0.79)$	0.255
ΔORİ 2	$-0.27 \pm 0.20$ (-0.26)	$-0.29 \pm 0.23$ (-0.23)	0.888
$\Delta PaO_2$ 1	319.48 ± 75.56 (333)	292.73 ± 76.65 (297)	0.048
$\Delta PaO_2 2$	$-$ 80.97 $\pm$ 81.78 (-84)	$-65.30 \pm 82.59$ (-57)	0.464

Values are presented as mean  $\pm$  standard deviation and median.

 $\Delta$ PaO<sub>2</sub> 1, PaO<sub>2</sub> change in T1-T2 time interval;  $\Delta$ PaO<sub>2</sub> 2, PaO<sub>2</sub> change in T2-T4 time interval;  $\Delta$ ORI 1, ORI change in T1-T2 time interval;  $\Delta$ ORI 2, ORI change in T2-T4 time interval.

Table 5	Comparison of mas	<pre>ventilation, BURP</pre>	maneuver and us	se of stylet and '	Videolaryngoscope.
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	Group L (n = 35)	Group H (n = 37)	р
Easy/Difficult MV	30/5 (85.7/14.3)	23/14 (62.2/37.8)	0.023
BURP maneuver +/-	10/25 (28.6/71.4)	20/17 (54.1/45.9)	0.028
Use of stylet +/-	8/27 (22.9/77.1)	18/19 (48.6/51.4)	0.023
Use of VL +/-	3/32 (8.6/91.4)	5/32 (13.5/86.5)	0.505

Values are presented as mean  $\pm$  standard deviation or number (%). MV, Mask Ventilation; VL, Videolaryngoscope.

high-risk OSA patients to better understand the relationship between ORi and  $PaO_2$ .

Patients with obstructive sleep apnea syndrome are at higher risk for hypoxia and hypercarbia due to factors such as obesity, altered lung mechanics, and airway obstruction during apnea periods.<sup>15</sup> Tsymbal et al.<sup>10</sup> reported that in obese patients, the ORi values at the end of preoxygenation and the beginning of intubation were significantly lower than those of patients with normal BMI, and the tolerable apnea time was also lower in obese patients. Although the tolerable apnea time was not evaluated in this study, ORi values at the end of preoxygenation, mask ventilation, and intubation were significantly lower in the high-risk group for OSA. This may be due to the negative impact of higher BMI on respiratory function in this group.

The relationship between tonsil size and the severity of sleep apnea is well-established in the literature.<sup>16</sup> In a study by Friedman et al,<sup>17</sup> tonsil size was associated with the severity of sleep apnea in 172 cases with suspected sleep apnea, with larger tonsil sizes indicating a higher severity of

the disorder. Additionally, studies have reported a significant decrease in the apnea-hypopnea index after tonsillectomy in adults, indicating the potential benefits of surgical intervention in patients with large tonsils and sleep apnea.<sup>18,19</sup> Consistent with these findings, in this study, patients in the high-risk group for OSA had larger tonsil sizes, which may have contributed to increased airway resistance, snoring, apnea, or hypopnea, ultimately leading to a higher STOP-Bang score.

The relationship between sleep apnea and difficult airway was first reported by Hiremath et al.,<sup>20</sup> and it was found that the apnea-hypopnea index was higher in patients with difficult intubation. Most studies examining the relationship between difficult airways and OSA used polysomnography, the gold standard for diagnosing OSA. Instead, the STOP-Bang questionnaire is used to screen patients for OSA, as polysomnography may not be readily available or feasible in certain settings. In a study comparing STOP-Bang scores and polysomnography results in the surgical population, patients with a score of 6 and above were determined to have a high probability of moderate/severe OSA.<sup>21</sup>

A meta-analysis of 72,888 patients reported that patients with OSA had a 3.39-fold higher rate of Difficult Mask Ventilation (DMV) than those without (1.48% vs. 1.11%, respectively). The same study also stated that the risk of difficult intubation increased in OSA patients, and the incidence of this condition increased as the severity of OSA increased (39% mild to moderate and 23% severe OSA).<sup>3</sup> In another study conducted with patients over 45 years of age, the risk of difficult intubation was shown to increase in patients diagnosed with moderate or severe OSA by preoperative polysomnography and with a STOP-Bang score of 3 and above, and DMV was only associated with neck circumference.<sup>22</sup> A study investigating the STOP-Bang questionnaire's role in predicting difficult intubation showed that the frequency of difficult intubation increased in patients with a score of 3 and above.<sup>23</sup> In a single-center study evaluating 307 patients who underwent elective surgery with the STOP-Bang score, the rate of difficult intubation was found to be 28.6% in the high-risk group (> 3 points), while it was not observed in the low-risk group (0-2 points).<sup>24</sup> In our study, the same physician provided the airway of all patients. Although difficult mask ventilation was seen significantly more frequently (37.8%) in high-risk patients, no significant relationship was found with difficult intubation, unlike the literature. The rate of difficult intubation was 13.5% in the highrisk patient group. Although the difference between the two groups regarding the need for a video laryngoscope was insignificant, the use of stylet and the need for Burp maneuver were higher in the high-risk patient group.

Our study has several limitations. First, patients with pulmonary or cardiac comorbidities were excluded, and further studies are necessary to evaluate the efficacy of ORi monitoring in these high-risk patients. Second, the study only used a standard preoxygenation method, and the effect of different preoxygenation methods on patients at risk of OSA was not examined. Third, the data may not be sufficient to estimate the relationship between SpO<sub>2</sub>, ORi, and PaO<sub>2</sub> in cases of unexpectedly difficult airways or prolonged apnea duration, as standard difficult airway preparation was applied to each patient. Fourth, the risk of OSA is also present in non-obese patients, but this study was planned without excluding the obesity factor. Finally, the study did not follow up with ORi in the postoperative period, which may have been necessary to monitor patients at risk of hypoxia.

In conclusion, according to the STOP-Bang score, patients at risk of OSA may have a difficult airway, and monitoring ORi in the perioperative period could be useful in managing possible hypoxic conditions in these patients. Although there were no patients with very high stop bang scores in our study, the decrease in ORI during apnea was significantly greater in the high-risk group, so our study provides preliminary evidence that ORi monitoring may be useful in managing perioperative oxygenation in patients at risk for OSA. Furthermore, future studies could explore different preoxygenation methods, the effects of ORi monitoring in patients with pulmonary or cardiac comorbidities, and the long-term outcomes of ORi monitoring in patients at risk for OSA.

# **Declaration of Competing Interest**

The authors declare no conflicts of interest.

#### **CRediT authorship contribution statement**

Ilka D. Alp: Conceptualization, Data curation, Formal analysis, Investigation, Project administration. Bengü G. Köksal: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Visualization, Writing – original draft, Writing – review & editing. Keziban Bollucuoğlu: Methodology, Resources, Supervision. Gamze Küçükosman: Writing – review & editing. Özcan Pişkin: Writing – original draft, Writing – review & editing. Çağdaş Baytar: Conceptualization, Formal analysis, Methodology. Rahşan D. Okyay: Conceptualization, Methodology. Hilal Ayoğlu: Supervision.

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### Data availability

The datasets analyzed during the current study are available from the corresponding author on reasonable request.

# Ethical approval number

2020-22/16 (The institutional review board of Zonguldak Bülent Ecevit University; meeting date: 18/11/2020).

# Clinical trial registration number

NCT05640856 (https://clinicaltrials.gov/ct2/results?cond=&term=+NCT05640856&cntry=&state=&city=&dist=).

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