

# Evaluation of the Effect of APFEL Risk Score and Fasting Times on Postoperative Nausea and/or Vomiting

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## Abstract

**Aim:** Postoperative nausea and vomiting (PONV) occurs in 30-80% of elective surgeries depending on the method of anesthesia, type of surgery and patient characteristics. It has been shown that prolonged preoperative fasting may increase rather than prevent complications. The aim of this study was to determine the relationship between APFEL risk score and duration of fasting and development of PONV.

**Methods:** A descriptive and observational study. This study was conducted between February and December 2023 in 321 patients scheduled for elective surgery at a university and a state hospital. Inclusion criteria included being over 18 years of age, having an ASA (American Society of Anesthesiologists) score between I-III, and voluntary participation in the study. Data were collected using the "Personal Information Form", "APFEL Risk Score" and "Post Operative Nausea and Vomiting Assessment Form". Statistical analyses were performed with IBM SPSS Statistics 27 program and  $p < 0.05$  was considered significant.

**Results:** The mean age of the patients was  $46.75 \pm 16.88$  years and 53.9% were female. The mean duration of solid food fasting was  $15.59 \pm 15.86$  hours and the mean duration of liquid food fasting was  $11.49 \pm 5.03$  hours. APFEL risk score of 2 was found in 33.3% of the participants. A statistically significant correlation was found between APFEL risk score, solid and liquid fasting times and ASPC ( $p < 0.05$ ). Patients who underwent gastrointestinal surgery had significantly longer fasting times ( $p < 0.05$ ).

**Conclusions:** APFEL risk score and fasting periods were found to be effective in the development of PONV. Appropriate regulation of preoperative fasting times may reduce the risk of PONV.

**Keywords:** *Apfel Risk Score; Nursing; Preoperative Fasting; Postoperative Nausea and Vomiting*

## 1. Introduction

Nausea and/or vomiting (PONV) in the first 24 hours after surgery is one of the most common reasons for delayed discharge.<sup>1-7</sup> The incidence of PONV after elective surgeries varies between 30-80% depending on the type of anesthesia, type of surgery and patient risk factors.<sup>1,4,8-11</sup> PONV is not only uncomfortable for the patient, but is also directly related to patient dissatisfaction. However, PONV can lead to serious complications such as dehydration, electrolyte and acid-base imbalances, pulmonary aspiration, pneumothorax, hypoxia, esophageal rupture, increased intracranial pressure, wound problems, bleeding, delayed oral intake, prolonged hospitalization, fatigue, anxiety, unexpected hospital readmissions and increased healthcare costs.<sup>2,4,12-14</sup> Therefore, prevention and effective management of perioperative nausea and/or vomiting in surgical patients is of great importance. Prevention of PONV is considered a critical goal in terms of early discharge, patient comfort, reduction of complications and

efficiency of healthcare services.<sup>2,4,12-14</sup>

In the preoperative period, patients' risk of nausea and/or vomiting should be assessed using standardized measurement tools.<sup>11</sup> A prevalent approach is the utilization of Apfel risk scoring, a method that has been instrumental in achieving a substantial decline in PONV rates.<sup>15</sup> The risk of PONV varies depending on the patient, the type of anesthesia, and the surgery performed. Noteworthy patient-related risk factors include female gender, young age, non-smoking status, and a history of PONV or motion sickness.<sup>3,16</sup> Anesthesia-related risk factors encompass the type of anesthesia administered, the duration of the procedure, the utilization of volatile anesthetics and nitrous oxide, and perioperative opioid use. In regard to surgical factors, it has been documented that the prevalence of PONV is elevated following laparoscopic, bariatric, gynecologic, and cholecystectomy procedures.<sup>2,13</sup>

In order to prevent the development of postoperative complications, such as nausea, vomiting, and aspiration pneumonia, patients should fast for a certain period of time before surgery. A light meal can be consumed up to 6 hours before elective procedures requiring general anesthesia, regional anesthesia or procedural sedation and analgesia, and clear fluids containing carbohydrates up to 2 hours before. However, it is imperative that these periods of preoperative fasting do not extend to a duration that might result in adverse outcomes for patients.<sup>17-21</sup> The extant literature has demonstrated that protracted preoperative fasting periods may, in fact, engender complications rather than prevent them. Therefore, it has been emphasized that patients should not be required to fast for unnecessarily long periods.<sup>22</sup>

It has been shown that PONV rates are higher in patients who were fasted for 12-24 hours preoperatively compared to patients who were fasted for a short time and given oral carbohydrate-containing fluids.<sup>23</sup> A multitude of studies have indicated that decreasing the preoperative fasting period can lead to a number of beneficial outcomes for patients. These include the elimination of patient-reported feelings of thirst, a reduction in symptoms of nausea and vomiting, an alleviation of anxiety, an enhancement of patient comfort, an acceleration of recovery, and a significant reduction in the duration of hospitalization.<sup>24-26</sup> Moreover, a reduced fasting period has been shown to decrease nitrogen loss through urine, prevent loss of muscle strength, reduce anxiety and thirst in the perioperative period, and prevent nausea and vomiting in the early postoperative period, thereby enhancing patient comfort.<sup>22,24</sup> On the other hand, in terms of level of evidence, it is reported that there are limited number of clinical studies explaining the relationship between preoperative fasting time and PONV.<sup>2</sup> Therefore, determining the relationship between risk factors and preoperative fasting times stands out as an important issue in terms of PONV prevention.

This study aimed to evaluate the impact of the APFEL risk score and preoperative fasting duration on PONV. It also highlights the importance of evidence-based risk assessment in high-risk patients and suggests minimizing prolonged fasting while encouraging appropriate prophylactic measures in at-risk individuals.

## 2. Materials and Methods

### 2.1. Design

A descriptive and observational study design was adopted. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist was used in the study process.<sup>27</sup>

### 2.2. Participants and Settings

This prospective study was conducted in the surgical departments of a university hospital and a state hospital from February 2023 to January 2024. We enrolled 321 patients undergoing elective surgery who met our inclusion criteria and provided informed consent. Post-hoc power analysis demonstrated 93% statistical power with an effect size of 0.5 and alpha level of 0.05. Eligible participants were those scheduled for elective surgery, admitted at least 6 hours before their procedure, classified as ASA I-III, undergoing general anesthesia, without visual or hearing impairments, without chronic pain conditions, and with no history of alcohol or substance abuse. The study excluded patients requiring emergency surgery or postoperative intensive care.

### 2.3. Data Collection Tools

"Personal Information Form," "Apfel Risk Score" and "Nausea and Vomiting Assessment Form" were used for data collection.

### 2.4. Personal Information Form

This form was prepared by the researchers according to the literature and consisted of 11 questions related to age, sex, body

mass index (BMI), type of surgery, duration of surgery, ASA score, time of last solid and liquid intake (preoperative fasting time), preoperative hunger and thirst score as perceived by the patient (0-10).<sup>2,4,11,13</sup>

### 2.5. Apfel Risk Score

Apfel's model is based on adult patients. Four distinct risk factors have been proposed in this model. These are female sex, history of PONV and/or motion sickness, non-smoking, and postoperative opioid use. Each risk factor is worth 1 point. The Apfel model suggests that each factor increases the risk of PONV by 20%. Even if there are no risk factors (score=0), the risk of PONV is 10%. If the risk score is 0, the risk of PONV is 10% and the risk is low. If the risk score is 1, the risk is 20% and the risk is low. If the risk score is 2, the risk is 40% and the risk is moderate. If the risk score is 3, the risk is 60% and the risk is high. If the risk score is 4, the risk is 80% and the risk is high.<sup>8,16</sup>

### 2.6. Nausea and Vomiting Assessment Form

PONV was assessed using a standardized protocol. Symptoms were recorded as present (Yes) or absent (No) for nausea, gagging, and vomiting, with a separate "None" category indicating complete absence of symptoms. Evaluations were conducted at five postoperative intervals: 0-2 hours, 2-4 hours, 4-8 hours, 8-12 hours, and 12-24 hours. The presence of antiemetic treatment was recorded.<sup>28</sup> There is no standard practice for nausea and vomiting management in clinics. However, nausea and vomiting management is organized according to the patient and the type of surgery.

### 2.7. Data collection procedure

The study data were collected by researchers for all eligible participants beginning the day before surgery. PONV was actively monitored for 24 hours following the surgical procedure. During times when researchers were not present in the hospital (such as overnight), PONV data were retrospectively collected from patient follow-up forms the following day.

### 2.8. Ethical Considerations

Permission was obtained from the non-interventional clinical research ethics committee (Date/no 22.07.2022/62), the head physician of the university hospital (Date/no 31.01.2023/E-18649120-622.03-628926), state hospital (Date/no 11.05.2023/31/ E-66442466-604.01.01-215653867), and the participants to conduct the study. In addition, the study was conducted in accordance with the principles of the Declaration of Helsinki 2008. The study was registered in ClinicalTrials (Clinicaltrials.gov: NCT00578006).

### 2.9. Data Analysis

The statistical analysis was performed using SPSS version 27. Frequency distributions and descriptive statistics were computed to summarize the data. For normally distributed continuous variables comparing two independent groups, Independent Samples t-tests were applied. Non-normally distributed data involving three or more independent groups were analyzed using Kruskal-Wallis H tests, with Mann-Whitney U tests conducted for post-hoc pairwise comparisons when significant differences were detected. Relationships between normally distributed quantitative variables were assessed using Pearson correlation coefficients. Throughout all analyses, a p-value threshold of <0.05 was established to determine statistical significance.

## 3. Results

The study population (n=321) had a mean age of 46.75±16.88 years, with 53.9% female representation. Most participants (69.2%) underwent non-gastrointestinal surgical procedures. Preoperative fasting durations averaged 15.59±15.86 hours for solids and 11.49±5.03 hours for liquids, with 97.8% of patients exceeding the

recommended minimum fasting thresholds (>6 hours for solids, >2 hours for liquids). Risk assessment using the Apfel score showed one-third of participants (33.3%) had a score of 2, corresponding to a 40% risk of postoperative nausea and vomiting (PONV). Only 8.1% of patients received antiemetics and this treatment was Metoclopramide. The mean duration of surgery was  $109.32 \pm 70.26$  minute, and the mean perceived hunger and thirst were  $2.63 \pm 2.86$  and  $4.20 \pm 3.11$  (0-10 points), respectively (Table 1).

The analysis revealed significant associations between preoperative fasting durations, Apfel risk scores, and postoperative nausea and vomiting (PONV) development. Both solid and liquid fasting durations showed time-dependent effects on PONV incidence. Solid fasting periods significantly influenced PONV occurrence at 2-4 hours ( $p=0.0001$ ), 4-8 hours ( $p=0.008$ ), and 12-24 hours ( $p=0.042$ ), while liquid fasting durations affected PONV at 2-4 hours ( $p=0.0001$ ), 4-8 hours ( $p=0.002$ ), and 12-24 hours ( $p=0.049$ ). No significant association was found for either fasting measure during the 8-12 hour interval ( $p>0.05$ ). The Apfel risk score demonstrated the strongest and most consistent association with PONV across all measured time points (all  $p \leq 0.0001$  except 12-24 hours at  $p=0.013$ ). Patients undergoing gastrointestinal surgery had significantly longer preoperative fasting durations for both solids ( $p=0.023$ ) and liquids ( $p=0.043$ ) compared to non-GI surgeries, though their Apfel risk scores did not differ significantly ( $p=0.292$ ) (Table 2). These findings highlight the differential impact

of fasting durations and the predominant role of Apfel risk scores in predicting PONV development.

The study examined the association between preoperative fasting durations, Apfel risk scores, and postoperative nausea and vomiting (PONV) across different time intervals (Table 3). The Apfel risk score demonstrated a significant positive correlation with PONV development during all postoperative periods ( $p<0.01$ ), with particularly strong associations observed at 0-2 hours ( $r=0.315$ ), 2-4 hours ( $r=0.330$ ), and 4-8 hours ( $r=0.239$ ), confirming its value as a key predictive tool for PONV risk. While fasting durations showed generally weaker correlations with PONV compared to the Apfel score, significant relationships were identified at specific time points. Both solid ( $r=0.201$ ) and liquid ( $r=0.181$ ) fasting times were positively associated with PONV during the immediate postoperative period (2-4 hours,  $p<0.01$ ). At 4-8 hours, liquid fasting duration ( $r=0.226$ ) exhibited a stronger correlation than solid fasting ( $r=0.123$ ). Weak but statistically significant associations were found for both fasting measures at 12-24 hours (solid:  $r=0.146$ ; liquid:  $r=0.144$ ). No significant relationship was observed between fasting durations and PONV at the 8-12 hour interval ( $p>0.05$ ). These findings suggest that while preoperative fasting durations influence PONV risk, their impact varies across different postoperative phases and is generally less pronounced than that of the Apfel risk score.

**Table 1**

Descriptive characteristics of patients

Variables (n=321)	n	%
Age [ $\bar{X} \pm SD \rightarrow 46.75 \pm 16.88$ (year)]		
BMI [ $\bar{X} \pm SD \rightarrow 27.03 \pm 5.09$ (kg/m <sup>2</sup> )]		
Sex		
· Male	148	46.1
· Female	173	53.9
Type of Surgery		
· GIS surgery*	99	30.8
· Non-GIS Surgery	222	69.2
ASA score [ $\bar{X} \pm S.D. \rightarrow 2.15 \pm 6.64$ ]		
· Urgent	4	1.2
· 1	76	23.7
· 2	227	70.7
· 3	14	4.3
Solid fasting [ $\bar{X} \pm S.D. \rightarrow 15.59 \pm 15.86$ (hour)]		
· 0-6 h	7	2.2
· 6 hours and above	314	97.8
Liquid fasting [ $\bar{X} \pm S.D. \rightarrow 11.49 \pm 5.03$ (hour)]		
· 0-2 hours	7	2.2
· 2 hours and above	314	97.8
Apfel risk score		
· 0 (10% risk)	76	23.7
· 1 (20% risk)	106	33.0
· 2 (40% risk)	107	33.3
· 3 (60% risk)	31	9.7
· 4 (80% risk)	1	0.3
Antiemetic treatment		
· Yes	26	8.1
· No	295	91.9
	X+SD	[Min.-Max.]
Duration of surgery (minute)	109.32±70.26	15-510
· Feeling hunger	2.63±2.86	0-10
· Feeling thirst	4.20±3.11	0-10

\*GIS: Gastrointestinal system surgery;  $\bar{X}$ =Mean, SD=Standart deviation

**Table 2**

Comparison of PONV and APFEL risk scores and preoperative fasting time

PONV	n	Solid fasting		Liquid fasting		APFEL Risk Score
		%	$\bar{X} \pm S.D.$	$\bar{X} \pm S.D.$	$\bar{X} \pm S.D.$	
0-2nd hour						
· None	105	32.7	14.55±9.21	10.54±3.23	0.73±0.76	
· Nausea	148	46.1	15.64±10.13	11.55±7.81	1.42±0.88	
· Gagging	46	14.3	21.78±42.77	12.25±5.75	1.44±0.99	
· Vomiting	22	6.9	14.58±4.50	12.58±4.83	1.81±0.91	
Test statistics*			$\chi^2=3.272$	$\chi^2=3.377$	$\chi^2=46.845$	
p			p=0.352	p=0.337	p=0.0001	
In-group <sup>a,b,c</sup>					(a,b,c)	
2-4th hour						
· None	134	41.7	12.47±3.61	10.08±3.38	0.87±0.82	
· Nausea	113	35.2	15.99±11.31	11.86±7.93	1.45±0.94	
· Gagging	17	5.3	14.43±2.41	12.72±3.19	1.28±0.91	
· Vomiting	57	17.8	26.63±44.74	13.11±6.77	1.63±0.92	
Test statistics*			$\chi^2=24.942$	$\chi^2=15.231$	$\chi^2=41.213$	
p			p=0.0001	p=0.0001	p=0.0001	
In-group <sup>a,b,c,d</sup>			(a,c,d)	(b,c)	(a,b,c,d)	
4-8th hour						
· None	183	57	13.29±4.22	10.20±3.27	0.99±0.89	
· Nausea	89	27.7	20.60±35.81	12.13±5.27	1.65±0.83	
· Gagging	12	3.7	13.75±2.31	12.62±2.26	1.12±0.83	
· Vomiting	37	11.5	20.79±18.39	14.64±12.41	1.51±1.01	
Test statistics*			$\chi^2=11.824$	$\chi^2=14.726$	$\chi^2=40.502$	
p			p=0.008	p=0.002	p=0.0001	
In-group <sup>a,c,d</sup>			(a,c)	(a,c)	(a,c,d)	
8-12th hour						
· None	208	64.8	15.53±10.66	11.64±6.84	1.10±0.92	
· Nausea	95	29.6	18.34±32.01	11.14±5.06	1.47±0.93	
· Gagging	5	1.6	13.00±0.81	11.25±1.70	1.00±0.81	
· Vomiting	13	4.0	14.60±3.89	11.80±5.22	1.50±1.08	
Test statistics*			$\chi^2=2.599$	$\chi^2=1.194$	$\chi^2=32.631$	
p			p=0.458	p=0.754	p=0.0001	
In-group <sup>a,c,d</sup>					(a,c)	
12-24th hour						
· None	306	95.3	14.99±9.81	11.17±5.82	1.19±0.91	
· Nausea	12	3.7	36.51±71.72	14.84±8.71	1.91±0.79	
· Gagging	-	-	-	-	-	
· Vomiting	3	0.9	17.10±6.42	15.10±7.73	2.00±1.00	
Test statistics*			$\chi^2=6.319$	$\chi^2=6.012$	$\chi^2=8.677$	
p			p=0.042	p=0.049	p=0.013	
In-group <sup>a</sup>			(a)	(a)	(a)	
Type of Surgery						
· GiS surgery	99		20.05±27.67	12.62±7.66	1.22±0.80	
· Non-GiS Surgery	222		13.60±3.47	10.98±3.13	1.33±1.00	
Test statistics			t=2.313	t=2.048	t=-1.057	
p			p=0.023	p=0.043	p=0.292	

\*a;  $p < 0.05$  for comparison between no and nausea \*b;  $p < 0.05$  for comparison between no and gagging \*c;  $p < 0.05$  for comparison between no and vomiting \*d;  $p < 0.05$  for comparison between nausea and gagging

\*In data with normal distribution, the "Independent Sample-t" test (t-table value) statistics were used to compare the measurement values of two independent groups. In data without normal distribution, the "Kruskal-Wallis H" test ( $\chi^2$ -table value) statistics were used to compare three or more independent groups.

**Table 3**

Correlations between preoperative fasting time, APFEL risk score and PONV

PONV	r/p	Solid fasting	Liquid fasting	APFEL Risk Score
0-2nd hour	r	.067	.096	.315**
	p	.234	.085	.001
2-4th hour	r	.201**	.181**	.330**
	p	.001	.001	.001
4-8th hour	r	.123*	.226**	.239**
	p	.028	.001	.001
8-12th hour	r	.022	.004	.249**
	p	.706	.944	.001
12-24th hour	r	.146*	.144*	.188**
	p	.045	.048	.010

*"Pearson" correlation coefficient was used to examine the relationships of two quantitative variables with normal distribution.*

*\*\*Correlation is significant at the 0.01 level (2-tailed).*

*\*Correlation is significant at the 0.05 level (2-tailed).*

#### 4. Discussion

This study investigated the impact of Apfel risk scores and preoperative fasting durations on PONV. The findings of the study indicated that the fasting times of the participants for solid and liquid food were greater than the recommended periods. The majority of patients exhibited solid fasting times that exceeded 6 hours and liquid fasting times that surpassed 2 hours. This finding aligns with the existing literature, which has also demonstrated that preoperative solid and liquid nutrient fasting times exceed the recommended limits.<sup>28-33</sup> The primary objective of preoperative fasting is to avert the occurrence of vomiting, regurgitation, and the aspiration of acidic gastric contents during the induction of anesthesia.<sup>32</sup> Prolonged periods of fasting can result in dehydration, electrolyte imbalances, hypoglycemia, postoperative nausea and vomiting, and an augmented risk of acute kidney injury, particularly in the elderly population.<sup>34,35</sup> It has also been shown that prolonged fasting can lead to insulin resistance, which can increase the risk of postoperative infection.<sup>33</sup> The study found that patients were more bothered by thirst than hunger. Excessive preoperative fasting and subsequent dehydration can activate the body's stress response, adversely impacting surgical patients' well-being.<sup>36</sup> These effects include dehydration, reduced patient comfort, and amplification of the surgical stress response.<sup>37</sup> Current guidelines state that solid food intake can continue up to 6 hours postoperatively and clear liquid intake up to 2 hours postoperatively.<sup>17-21,32,36,38</sup> Despite these recommendations, our study consistent with prior literature found that actual fasting durations routinely exceed these thresholds. Patients may remain hungry and thirsty from midnight before surgery until the time of surgery.<sup>33, 37,39</sup> "Nil per os" is still widely practiced in many institutions for all patients scheduled for surgery the next day. Contrary to current recommendations, it is thought that this traditional practice is still practiced in the study sample.

Analysis of preoperative fasting times revealed significant associations between solid/liquid fasting durations and postoperative nausea and vomiting (PONV), particularly in the 2-4, 4-8, and 12-24 hour intervals. Notably, patients who experienced vomiting within 2-4 hours had significantly longer solid fasting times, suggesting that excessively prolonged fasting may impair

gastrointestinal motility, thereby increasing PONV risk. Similarly, extended fasting was linked to higher nausea and vomiting rates at 4-8 and 12-24 hours, reinforcing the adverse effects of inadequate fasting management.

Current literature lacks sufficient studies focusing solely on the relationship between preoperative fasting time and postoperative nausea and vomiting (PONV). PONV is influenced by multiple factors, including patient characteristics, anesthesia techniques, and surgical variables.<sup>13</sup> Among these, fasting duration remains a debated factor, with conflicting evidence on its impact. However, recent studies suggest that prolonged fasting may exacerbate PONV. Li et al. reported that surgical patients with shorter preoperative fasting periods had a significantly lower incidence of PONV.<sup>40</sup> Similarly, Şişman et al. identified a positive correlation between extended solid/liquid fasting times and PONV.<sup>28</sup> This trend is also observed in pediatric populations, where children with shorter fasting durations experienced significantly fewer episodes of postoperative vomiting.<sup>41</sup> These findings align with the present study's results, underscoring the importance of optimized preoperative fasting protocols to mitigate PONV risk.

Our findings demonstrate that the Apfel risk score represents the most robust predictor of postoperative nausea and vomiting (PONV), with statistically significant associations observed across all postoperative time periods. This conclusion is supported by multiple studies: Kirtıl et al. found significantly higher Apfel scores in patients experiencing vomiting<sup>31</sup>, while Şişman et al. documented a clear positive correlation between increasing Apfel scores and PONV incidence.<sup>28</sup> Current evidence strongly supports a risk-adapted approach to PONV management. A 2020 literature review by Kranke et al. established that risk-stratified antiemetic prophylaxis constitutes the optimal strategy for PONV prevention.<sup>42</sup> These findings align with the Fourth Consensus Guidelines (2020), which recommend multimodal antiemetic therapy for patients presenting with multiple risk factors.<sup>2</sup> Effective PONV prevention requires a systematic approach beginning with standardized preoperative patient evaluation. Routine implementation of validated risk assessment tools (such as the Apfel score) for all surgical patients,<sup>2,14,16</sup> collaboration among surgical teams to ensure appropriate, risk level-specific prophylaxis, and development of comprehensive institutional protocols for PONV management may be recommended.

##### 4.1. Study Limitations

This study has some limitations. Since the sample size was smaller in some subgroups (especially in patients with gagging and vomiting), the generalizability of the results obtained in these groups may be limited. Finally, the study did not fully control for potential confounding factors such as the characteristics of different surgical procedures and anesthesia management.

#### 5. Conclusion

This study demonstrated the effects of preoperative fasting times and APFEL risk score on the development of PONV. The study revealed that solid and liquid fasting times were longer than recommendations. In addition to the APFEL risk score being a strong predictor of PONV development, an increase in PONV was shown with prolonged solid and liquid fasting times. Preoperative fasting aims to reduce the volume and acidity of gastric contents, thus reducing the risk of regurgitation/aspiration. Traditional fasting is prolonged and patients are therefore prone to adverse complications. In addition to approaches based on individual risk factors, appropriate management of fasting times is an important strategy to prevent PONV. In-depth research should be conducted



to identify factors influencing fasting times and PONV, and the surgical team should be regularly trained on new guidelines and risk assessment strategies.

### Statement of ethics

Permission was obtained from the non-interventional clinical research ethics committee (Date/no 22.07.2022/62), the head physician of the university hospital (Date/no 31.01.2023/E-18649120-622.03-628926), state hospital (Date/no 11.05.2023/31/ E-66442466-604.01.01-215653867), and the participants to conduct the study. In addition, the study was conducted in accordance with the principles of the Declaration of Helsinki 2008. The study was registered in ClinicalTrials (Clinicaltrials.gov: NCT00578006).

### genAI

Artificial intelligence (AI)-assisted technologies (such as Large Language Models [LLMs], chatbots, or image creators) were not used in the production of this article.

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### Conflict of interest statement

The authors declare that they have no conflict of interest.

### Availability of data and materials

This Data and materials are available to the researchers

### Author contributions

DG, IY: conceptualization, methodology, investigation, and writing – original draft. DG, IY: resources, formal analysis, and writing – review and editing. DG, IY: conceptualization, methodology, and writing – review and editing. All authors read and approved the final version of the manuscript.

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