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ORIGINAL ARTICLE

Integrated pulmonary index in pediatric sedation for endoscopy: a prospective cohort study

Índice pulmonar integrado en sedación pediátrica para endoscopia: estudio de cohorte prospectivo

Ruslan Abdullayev[1], Yavuz Kelleci[2], Adem Halis[3], Sevket Girgin[4], Ayten Saracoglu[5,6], and Tumay Umuroglu[1]*

[1]Department of Anesthesiology and Reanimation, Marmara University School of Medicine; [2]Department of Anesthesiology and Reanimation, Marmara University Training and Research Hospital; [3]Department of Anesthesiology and Reanimation, Koç University Hospital; [4]Department of Public Health, Marmara University School of Medicine. Istanbul, Turkey; [5]Department of Anesthesiology, ICU and Perioperative Medicine, Hamad Medical Corporation; [6]Department of Anesthesiology, Qatar University College of Medicine. Doha, Qatar

Abstract

Objective: *Integrated pulmonary index (IPI™) is a device working with fuzzy logic principle that analyzes patient's end-tidal carbon dioxide ($ETCO_2$), respiratory rate (RR), peripheral oxygen saturation (SpO_2), and pulse rate and provides a number between 1 and 10. We aimed to investigate the usefulness of IPI monitor in pediatric patients.* **Methods:** *After the Investigational Review Board approval pediatric patients undergoing gastrointestinal endoscopy under sedation were recruited. Propofol (Group P) and ketamine (Group K) were used for sedation. The primary outcome measure was average periprocedural IPI values. Secondary outcome measures were recovery time, endoscopist, and anesthetist satisfactions. Correlation of IPI values with physiological parameters was examined as well.* **Results:** *Periprocedural IPI scores were comparable between the groups (6.3 [4.9-7] vs. 6.8 [5.3-7.6] in Group P and Group K, respectively, $p = 0.153$). Recovery time was significantly longer in Group K ($p < 0.001$). Endoscopist and anesthetist satisfaction scores were comparable. Low IPI scores were significantly associated with low $ETCO_2$, RR, and SpO_2 values ($p < 0.001$).* **Conclusions:** *IPI monitor is a valuable tool in the monitorization of the pediatric patients undergoing sedation with propofol and ketamine. Both drugs are associated with comparable IPI scores. $ETCO_2$, RR, and SpO_2 values are measured lower in patients with low IPI scores (1-3 points).*

Keywords: *Gastrointestinal. IPI. Ketamine. Non-operating room. Propofol.*

Resumen

Objetivo: *El índice pulmonar integrado (IPI™) es un dispositivo que funciona con el principio de lógica difusa para analizar el dióxido de carbono al final de la espiración ($ETCO_2$), la frecuencia respiratoria (FR), la saturación periférica de oxígeno (SpO_2) y la frecuencia cardiaca (FC), y proporciona un número entre 1 y 10. Nuestro objetivo fue investigar la utilidad del monitor IPI en pacientes pediátricos.* **Métodos:** *Tras la aprobación por la Junta de Revisión de Investigaciones, se reclutaron pacientes pediátricos sometidos a endoscopia gastrointestinal bajo sedación. Para la sedación se utilizó propofol (grupo P) o ketamina (grupo K). La medida de resultado primaria fueron los valores medios del IPI periprocedimiento. Las medidas de resultado secundarias fueron el tiempo de recuperación y la satisfacción del endoscopista y del anestesista. También se examinó la correlación de los valores del IPI con los parámetros fisiológicos.* **Resultados:** *Las puntuaciones del IPI periprocedimiento fueron comparables entre los grupos (6.3 [4.9-7] en el grupo P frente a 6.8 [5.3-7.6] en el grupo K; $p = 0.153$). El tiempo de recuperación fue significativamente mayor en el grupo K ($p < 0.001$). Las puntuaciones de satisfacción del endoscopista y del*

***Correspondence:**
Ruslan Abdullayev
E-mail: ruslan_jnr@hotmail.com

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anestesista fueron comparables. Unas puntuaciones bajas del IPI se asociaron significativamente con valores bajos de $ETCO_2$, FR y SpO_2 ($p < 0.001$). **Conclusiones:** *El monitor IPI es una herramienta valiosa para la monitorización de los pacientes pediátricos sometidos a sedación con propofol o ketamina. Ambos fármacos se asocian a puntuaciones de IPI comparables. Los valores de $ETCO_2$, FR y SpO_2 son más bajos en pacientes con puntuaciones de IPI bajas (1-3 puntos).*

Palabras clave: *Gastrointestinal. IPI. Ketamina. Sala no quirúrgica. Propofol.*

Introduction

Respiratory depression and airway obstruction are the main causes of morbidity during sedation. Although pulse oximetry is a part of routine monitoring, it has disadvantages such as delayed display of arterial deoxygenation and lack of information about ventilation[1]. Capnography was found to be superior to pulse oximetry in detecting hypoventilation and airway obstruction, and the use of capnography decreased hypoxemia and apnea episodes during sedation[2-4]. Current clinical practice guidelines suggest that capnography should be used routinely, especially in moderate and deep sedation where verbal communication with patients cannot be maintained[5-7].

The integrated pulmonary index (IPI™) is a commercially available tool developed to detect changes in respiratory status of patients during sedation. This software works with a principle using the fuzzy logic mathematical model algorithm[8]. It analyzes patients' physiological parameters such as end-tidal carbon dioxide ($ETCO_2$), respiratory rate (RR), peripheral oxygen saturation (SpO_2), and pulse rate (PR) together and displays a number between 1 and 10 on the monitor (Supplementary data table 1). Studies have shown that there is agreement between IPI values and clinical assessment of the patient's respiratory status[9]. Effects of many sedative drugs individually on IPI have still not been studied.

Propofol and ketamine are among the agents frequently used in endoscopy procedures. While propofol provides rapid recovery with its short half-life, it can cause severe hemodynamic instability and respiratory failure. On the other hand, ketamine causes less hemodynamic instability and less respiratory failure, but it may cause increased secretion, agitation on awakening, and prolonged recovery[10].

The aim of this study was to investigate the periprocedural IPI values in pediatric patients sedated with propofol and ketamine. The primary outcome measure was average periprocedural IPI values. The secondary outcome measures were recovery time, endoscopist, and anesthetist satisfactions. The hypothesis of the study was that the patients sedated with ketamine would have higher IPI values.

Methods

This study was approved by the Marmara University Faculty of Medicine Clinical Research Ethics Committee (Date: May 07, 2021/No: 09.2021.511) and recorded on the public website (https://clinicaltrials.gov/, No: NCT05137574). Pediatric patients undergoing elective upper and/or lower gastrointestinal endoscopy under sedation at our hospital between May 2021 and November 2021 were included in the study. Signed written informed consent was obtained from the patients' first-degree relatives or guardians. Inclusion criteria for the study were as follows: being older than 1 month and younger than 18 years of age and having American Society of Anesthesiologists (ASA) I-III physical status. Exclusion criteria were as follows: refusal to participate in the study, having an ASA IV or higher physical status, patients unsuitable for non-operating room anesthesia, and patients with a known allergy to drugs to be used for sedation. Anaphylactic reaction that may develop due to the drugs applied; respiratory failure requiring endotracheal intubation; hemodynamic failure; and gastrointestinal perforation, bleeding, or other major complications of endoscopy were determined as exclusion criteria from the study after the enrollment.

Patients were divided into two groups where propofol was used for sedation for the first group (Group P) and ketamine for the second (Group K). Patients were blind to the study design and did not know which group they would be in. The anesthetist administering the drugs and taking the measurements was the same and was not blinded to the study. The pediatric gastroenterologist performing the endoscopy procedure was blind to the study.

Routine monitoring, including pulse oximetry (SpO_2), three-lead electrocardiography, and non-invasive blood pressure, was performed after the patient entered the procedure room. A balanced crystalloid solution was started as an intravenous infusion at a rate of 10 mL/kg/h after a peripheral vascular access was placed. Midazolam 0.05 mg/kg intravenously (IV) was administered for sedation and anxiolysis. In addition,

a special nasal cannula (Smart CapnoLine Plus; Oridion Medical, Needham, MA, USA) for IPI was applied to the patient and connected to the monitor (Capnostream 20; Oridion Medical, Needham, MA, USA). Oxygen was administered at 2 L/min through the nasal cannula of the monitor. After the preparation of the surgical team was confirmed, remifentanil 0.5 μg/kg IV was administered. The patient was placed in the left lateral decubitus position and a mouthpiece was attached to the patient's mouth if upper endoscopy was to be performed. Then, propofol 0.5 mg/kg IV for Group P and ketamine 0.5 mg/kg IV for Group K was administered. The patient with a Ramsey Sedation Scale score of 5 or 6 (poor or no response to glabellar tapping) was handed over to the endoscopy team to perform the procedure. Additional doses of remifentanil 0.5 μg/kg IV, propofol 0.5 mg/kg IV (for Group P), and ketamine 0.5 mg/kg IV (for Group K) were added at the discretion of the anesthetist when needed.

Data were collected by the anesthetist performing the sedation procedure. Demographic and anthropometric measurements of the patient, ASA physical status, amount of drugs used, procedure, and recovery times were recorded. $ETCO_2$, RR, SpO_2, and PR values were recorded at 3-min intervals starting from the anesthetic induction of the patient. Our primary outcome measure was mean IPI values. The secondary outcome measures were recovery time, endoscopist and anesthetist satisfactions. The endoscopist and anesthesiologist satisfactions were graded according to the Likert scale between 1 and 10 points. Jaw-thrust maneuvers and number of bag-valve-mask assisted ventilations applied to the patient during the procedure were also recorded. Finally, the correlation of IPI values with $ETCO_2$, RR, SpO_2, and PR was analyzed. Individual IPI values were grouped as low IPI (IPI 1-3), medium IPI (IPI 4-6), and high IPI (IPI 7-10) and $ETCO_2$, RR, SpO_2, and PR values were compared between these groups.

Jamovi software (Version 2.3, https://www.jamovi.org) was used for statistical analysis. Categorical data were defined by number and percentage. Continuous data were defined as mean and standard deviation, or median and interquartile range for normal and non-normal distributions, respectively. Shapiro-Wilk test and histogram graphs were used for normality testing. X^2 test was used for the analysis of categorical data. Student's t and Mann-Whitney U-tests were used for the analysis of continuous data with normal and non-normal distributions, respectively. In the analysis of the continuous data regarding $ETCO_2$, RR, SpO_2, and PR according to the IPI score categories of the participants, Kruskal-Wallis test was used with Dwass-Steel-Critchlow-Fligner (DSCF) test for the pairwise comparisons. The independent variables of the study were age, gender, height, body weight, duration of procedure, midazolam dose, remifentanil dose, drug group, ASA score, type of intervention, and number of bag-valve-mask maneuvers. The dependent variables were $ETCO_2$, RR, SpO_2, PR, IPI scores, and IPI score categories. G*Power program (version 3.1) was used for power analysis of our study. Regarding the IPI score, which is the primary outcome measure of the study, with the α error of 5%, the power of the study being 80%, and the effect size of 0.75 obtained from the preliminary measurements on eight patients, the sample size was calculated to be 58.

Results

A total of 66 patients were eligible for the study, of which 60 were included in the final analysis. The flow diagram of the study is presented in figure 1. Thirty-six (60%) of the patients were female and the mean age was 13 (25th-75th percentiles: 9-15) years. Demographic and clinical characteristics of the patients are demonstrated in table 1. There was no significant difference between the two groups in terms of age, gender, height, body weight, ASA, type of intervention, amount of midazolam, and remifentanil used. There was no significant difference between the two groups in terms of the number of jaw-thrust maneuvers ($p = 0.06$, Mann-Whitney U-test). However, when categorizing the maneuver, a significant difference was observed between the groups, where the number of the patients not requiring the jaw-thrust maneuver was 4 (13.3%) and 13 (43.3%) in the Groups K and P, respectively ($p = 0.023$, X^2 test). The IPI scores were comparable between the groups (6.3 [4.9-7] vs. 6.8 [5.3-7.6] in Group P and K, respectively, $p = 0.153$, Mann-Whitney U-test). While there was no significant difference between the two groups in terms of procedure time, recovery time was significantly longer in Group K ($p < 0.001$). There was no significant difference between the two groups in terms of endoscopist and anesthetist satisfactions as well.

Descriptive statistics of IPI values and their corresponding physiological parameters are presented in figure 2 and Supplementary data table 2. Comparison of physiological parameters such as $ETCO_2$, RR, SpO_2, and PR between low, medium, and high IPI groups is given in table 2. While there was no

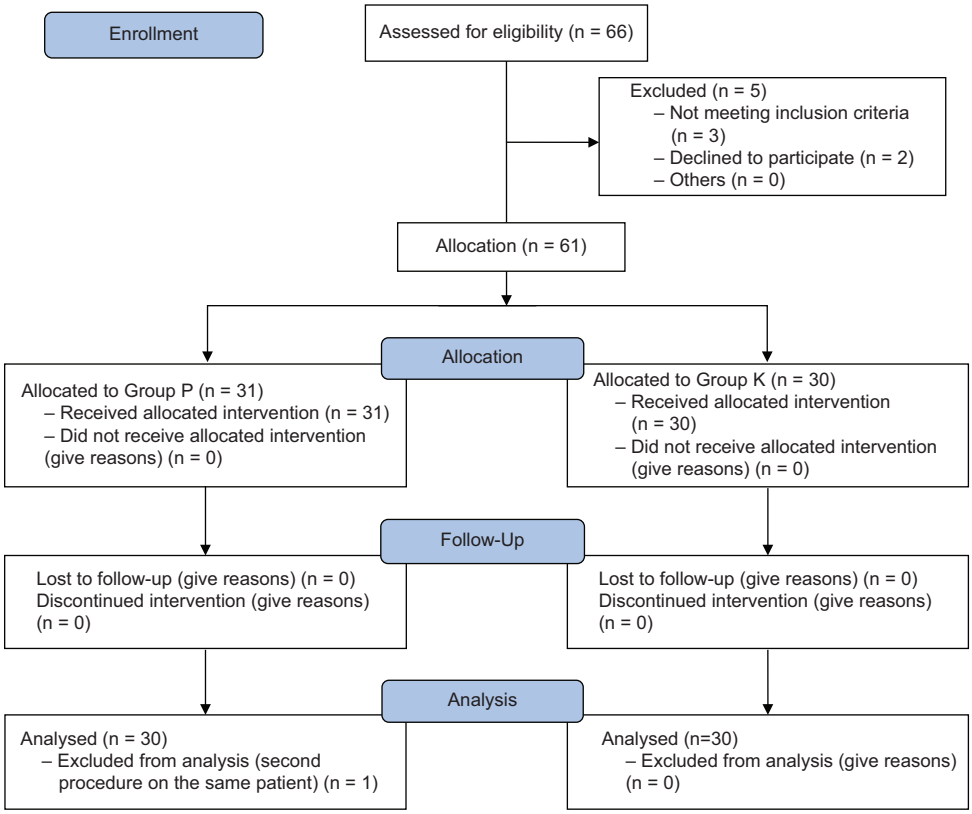

Figure 1. *Study flow diagram.*

difference between the IPI groups in terms of PR, a statistically significant difference was demonstrated between the low, medium, and high IPI groups in terms of $ETCO_2$, RR, and SpO_2 ($p < 0.001$, Kruskal-Wallis test). Pairwise comparisons between the groups revealed that $ETCO_2$ in the low IPI group was significantly lower compared to the other two ($p < 0.001$, DSCF test); SpO_2 in the high IPI group was significantly higher compared to the other two ($p < 0.001$, DSCF test); and RR values were significantly different between all the three groups ($p < 0.001$, DSCF test).

There were no complications in the patients related to the endoscopy procedure itself. Severe hypoxemia developed in two patients in Group K, in which assisted ventilation was provided with a bag-valve-mask, and the hypoxemia resolved in a short time. No bag-valve-mask ventilation was needed in Group P.

Discussion

We investigated the effectiveness of the IPI monitoring in pediatric patients sedated with propofol and ketamine and the main result of our study was that these drugs had comparable IPI scores. There was a good relationship between physiological parameters and IPI scores.

Cardiopulmonary complications continue to be important causes of morbidity and mortality in these procedures[11]. Current clinical practice guidelines recommend monitoring the hemodynamic and respiratory status of patients, as well as their state of consciousness during sedation procedures. The Association of Anesthetists recommends capnography monitoring whenever verbal communication with sedated patients is interrupted[7]. Many studies have shown that the use of capnography provides additional safety in addition to pulse oximetry[1,12,13]. Some studies have stated that derangements in respiratory pattern occurs before hypoxia develops and this can be detected by capnography[14,15]. IPI is a technology that has been introduced for more than a decade[8]. Although it has a complicated working principle like the fuzzy logic mathematical model, the value between 1 and 10 reflected on the monitor makes it extremely easy to use. In addition, grouping these values and using a three-point scale instead of a ten-point scale (low, medium, and high IPI corresponding to 1-3, 4-6, and 7-10 points, respectively) makes the use of the

Table 1. Demographic and clinical characteristics of the patients

Parameter	Group P	Group K	p
Age (years)	14.5 (10-15)	12.0 (7-13.75)	0.089
Sex			
Female	19 (52.8)	17 (47.2)	0.598
Male	11 (45.8)	13 (54.2)	
Height (cm)	153.5 (123.5-160.75)	142.5 (120-160)	0.424
Body weight (kg)	42.5 (25.75-50.75)	39.5 (19.25-52)	0.437
BMI (kg/m^2)	19 ± 5.29	18.5 ± 6.05	0.734
ASA			
I	14 (56.0)	11 (44.0)	0.715
II	13 (44.8)	16 (55.2)	
III	3 (50)	3 (50.0)	
Procedure			
Gastroscopy	21 (53.8)	18 (46.2)	0.066
Colonoscopy	8 (61.5)	5 (38.5)	
Gastroscopy + colonoscopy	1 (12.5)	7 (87.5)	
Midazolam amount (mg)	2.0 (1.5-2)	2.0 (1-2)	0.187
Remifentanil amount (µg)	40.0 (21.25-90)	30.0 (20.5-50)	0.609
Propofol/Ketamine amount (mg)	104.33 ± 50.03	72.50 ± 55.20	
IPI	6.3 (4.9-7)	6.8 (5.3-7.6)	0.153
Jaw-thrust maneuver (number)	1 (1-2) (0-6)	1 (0-2) (0-5)	0.06
0	4 (23.5)	13 (76.5)	0.023*
1	13 (68.4)	6 (31.6)	
≥ 2	13 (54.2)	11 (45.8)	
Procedure duration (min)	12.0 (10-22.5)	15.5 (10-29.5)	0.229
Recovery duration (min)	15.0 (13.5-20)	28.5 (25-30)	< 0.001*
Endoscopist satisfaction (1-10-point Likert scale)	10.0 (10-10)	10.0 (10-10)	0.190
≤ 6	1	0	
7-9	0	4	
10	29	26	
Anesthetist satisfaction (1-10-point Likert scale)	10.0 (8-10)	10.0 (10-10)	0.502
≤ 6	3	4	
7-9	6	2	
10	21	24	

*p < 0.05.
Categorical variables are given as number (percentage). Continuous variables are given as median (25th-75th percentiles) or mean ± standard deviation. For jaw-thrust maneuvers minimum-maximum values are given as well.
Group P: propofol used group; Group K: ketamine used group; BMI: body mass index; ASA: American Society of Anesthesiologist physical status; IPI: integrated pulmonary index.

Table 2. Distribution of physiological parameters according to low, medium, and high IPI groups

Parameter	Low IPI (1-3)	Medium IPI (4-6)	High IPI (7-10)	p
Number of measurements	71	85	257	
$ETCO_2$ (mmHg)	12[a] (0-34.5)	44 (35-49)	42 (36-47)	< 0.001*
RR (breaths/min)	2[b] (0-10)	13[b] (10-20)	19[b] (14-23)	< 0.001*
SpO_2 (%)	96 (86.5-100)	99 (97-100)	100[c] (99-100)	< 0.001*
PR (beats/min)	104 (85.5-125)	103 (82-128)	105 (90-116)	0.886

*p < 0.05.
[a]Significant difference compared to the medium and high IPI groups (p < 0.001, Dwass-Steel-Critchlow-Fligner (DSCF) test).
[b]Significant difference between all the IPI groups (p < 0.001, DSCF test).
[c]Significant difference compared to the low and medium IPI groups (p < 0.001, DSCF test).
Variables are given as median (25th-75th percentiles).
$ETCO_2$: end-tidal carbon dioxide; RR: respiratory rate; SpO_2: peripheral oxygen saturation; PR: pulse rate.

monitor even more practical. The use of the monitor in this way is more advantageous in cases where sedation is performed by the endoscopist or a nurse[11,16].

In our study, the mean IPI values were 6.3 in the propofol group and 6.8 in the ketamine group. Garah et al.[11] demonstrated that factors such as young age, use of propofol alone, high midazolam dose, and presence of an anesthesiologist were associated with low IPI values. In our study, we initially administered a standard dose of midazolam to the patients to benefit from its anxiolytic and amnestic properties. At the beginning of the procedure, we provided "balanced sedation" by applying remifentanil and the appointed intravenous anesthetic agent. The IPI values we obtained were consistent with the values in the propofol + midazolam or propofol + midazolam + fentanyl groups in the study of Garah et al.[11] In their study, the threshold value for the low midazolam dose was 0.08 mg/kg. In our study, we used midazolam at a dose of 0.05 mg/kg as a standard, and our IPI values were consistent with the low midazolam group in that study.

The presence of an anesthetist during the endoscopy procedure is a comfort for the endoscopy team. Evaluating the patient separately and creating a personalized anesthetic protocol not only increases the safety of the patient but also ensures the endoscopy team to focus on the endoscopy procedure itself. The American Society for Gastrointestinal Endoscopy recommends that endoscopists apply propofol-based sedation if it will increase patient safety, comfort, or the effectiveness of the procedure. According to the American Gastroenterological Association and Canadian Association of Gastroenterology guidelines, there is no increased risk associated with propofol administration by non-anesthetists[17,18]. Nevertheless, more than 20 European national anesthesia societies, including the Italian Society of Digestive Endoscopy and the Spanish Society of Anesthesia, have recommended the administration of propofol to be limited only to those trained in general anesthesia practice[19-21]. When deciding whether to provide the sedation by the endoscopy team, either by nurses or physicians, or by the anesthesia team, factors such as the patient's

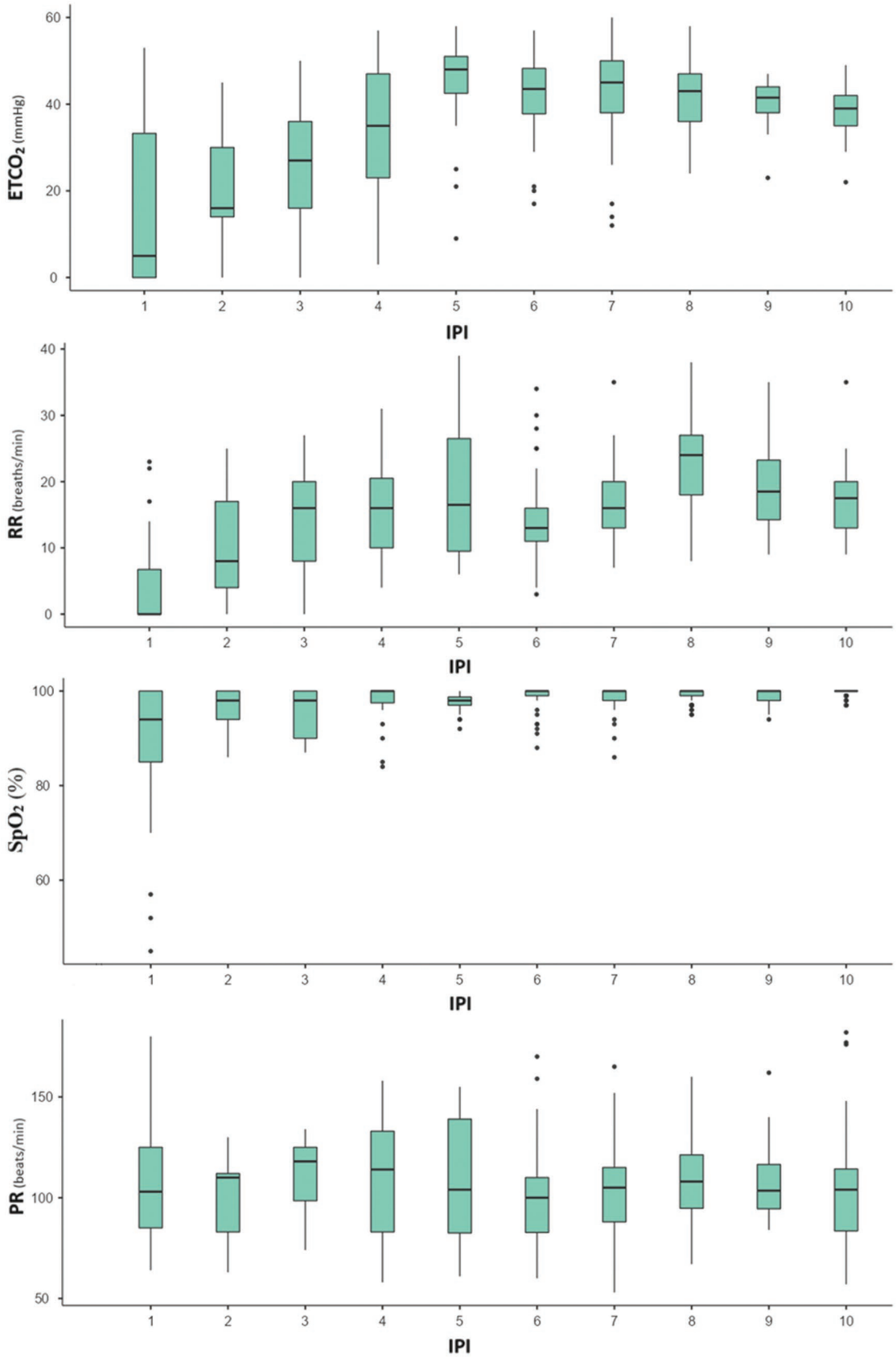

Figure 2. *Distribution of physiological variables with different IPI values. $ETCO_2$: end-tidal carbon dioxide; RR: respiratory rate; SpO_2: peripheral oxygen saturation; PR: pulse rate. Please note that IPI is determined by the combination of all the four parameters using the fuzzy logic principle.*

ASA physical status, comorbidities, the possibility of difficult airway or intubation, the types of drugs used, and probably less important factors such as the cost of the procedure should be considered altogether[22]. In our clinic pediatric endoscopy, procedures are routinely performed under sedation provided by the anesthesia team. We think that the endoscopist satisfaction scores in our study also reflect this practice.

In case of hypoxemia during the procedure nasal oxygen was increased, jaw-thrust maneuver was performed, and ventilation with bag-valve-mask was used if needed. No endotracheal intubation was needed in our study. The fact that the patient has an anesthesia team that only deals with sedation and the implementation of a protocol in accordance with the concept of balanced anesthesia played an important role here. While only two patients in the ketamine group were ventilated with a bag-valve-mask due to deep hypoxia, none of the patients in the propofol group required bag-valve-mask ventilation. In our study, the jaw-thrust maneuver was less in the ketamine group. Propofol, ketamine, dexmedetomidine, etomidate, midazolam, pentobarbital, and various combinations of these drugs are used for pediatric gastrointestinal endoscopy procedures. Each drug has its own advantages and disadvantages, and this should be considered. Propofol, especially when given as a bolus, may cause respiratory depression, apnea, and hemodynamic instability[23,24]. In a large review that examined the safety profile of propofol and included 17,066 patients, 9.3% of patients had desaturation, 1.9% had apnea, and 1.4% needed assisted ventilation[25]. Ketamine has advantages such as having analgesic effect, less respiratory depression, and not causing hemodynamic instability. Disadvantages include nausea, unpleasant recovery reactions, and rarely apnea or laryngospasm. Hallucinations usually occur in children over the age of 15. Apnea and laryngospasm occur in < 1% of patients[26,27]. Although ketamine generally preserves airway muscle tone and protective reflexes and does not suppress spontaneous breathing, desaturation is sometimes inevitable in the case of laryngospasm. Our findings were consistent with the literature.

Satisfaction scores of the team providing the sedation were also measured. The evaluation was made on parameters such as the patient's immobility, maintenance of spontaneous breathing, analgesia, no need for jaw-thrust, or assisted ventilation. There was no significant difference between the two groups in terms of anesthetist satisfaction. Even though ketamine, considering the above-mentioned characteristics, seems to be more advantageous, it is not surprising that the anesthetist who knows the pros and cons of both drugs achieves similar satisfaction scores with both drugs.

In our study, a statistically significant difference was found between low, medium, and high IPI groups in terms of $ETCO_2$, RR, and SpO_2. In the low IPI group, $ETCO_2$, RR, and SpO_2 values were below the physiological limits. This was an expected result when we consider the principle of the IPI's fuzzy logic model methodology. The expected effect of propofol is that the RR and subsequently SpO_2 decrease. Ketamine can lower SpO_2 for the reasons mentioned above. Respiratory depression has various effects on $ETCO_2$. Some studies have shown that there is an increase in $ETCO_2$ values with sedation[28,29]. However, insufficient CO_2 reaching the sample line with airway obstruction and hypoventilation will be associated with a low $ETCO_2$ reading[1]. It should be kept in mind that these measured CO_2 values do not reflect arterial CO_2 values and there may be significant differences between the two[30]. Arterial blood gas analysis should be used for the latest. The low $ETCO_2$ values in the low IPI group in our study were consistent with the findings of Berkenstadt et al.[1] In addition, RR and SpO_2 values were lower in the low IPI group in our study. Although reducing the IPI score, which we evaluate over ten scales, to three scales as low-medium-high makes the interpretation easier, it may deprive us of some valuable physiological parameters. This must be done very carefully as it may compromise the patient's follow-up.

Our study had few limitations. First, the same anesthetist provided sedation to the patient and measured the IPI scores. Blinding of this part of the study would have resulted in more objective approach to the IPI monitorization with two different drugs. Second limitation of our study was that we did not measure the level of sedation objectively. We do not routinely measure the sedation-anesthesia depth for non-operating room procedures, but in such a study, sedation depth monitoring with processed electroencephalography (EEG) could have been important in terms of the group homogeneity; yet keeping in mind that the processed EEG monitor could be unreliable in pediatric patients. Thirdly, we included both upper endoscopy and colonoscopies in the study. Anesthetic implications of these are different, specifically as regard to the airway control for the upper endoscopy and more need for analgesia for the colonoscopy. Selecting only one of these procedures for the study would have been more solid in terms of

the group homogeneity. Another is the age of the patients. We had a broad range of the age, and the pattern of the respiratory complications could have been dependent on the age, so it would be prudent to have a narrower age range for the patients. And finally, we did not measure the patients' pain levels objectively. Considering that ketamine has analgesic activity unlike propofol, having an objective pain scale would be valuable. Future studies may also include the measures of depth of sedation such as Bispectral Index and/or level of analgesia such as Analgesia Nociception Index.

Conclusion

IPI monitor is a valuable tool in the monitorization of the pediatric patients undergoing sedation for endoscopic procedures with propofol and ketamine. In this study, we found that both propofol and ketamine were associated with comparable IPI scores. IPI scores had good correlation with the physiological parameter routinely monitored; and $ETCO_2$, RR, and SpO_2 values were measured lower in the patients with low IPI scores (1-3 points).

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Conflicts of interest

The authors declare no conflicts of interest.

Ethical considerations

Protection of humans and animals. The authors declare that the procedures followed complied with the ethical standards of the responsible human experimentation committee and adhered to the World Medical Association and the Declaration of Helsinki. The procedures were approved by the Institutional Ethics Committee.

Confidentiality, informed consent, and ethical approval. The authors have followed their institution's confidentiality protocols, obtained informed consent from patients, and received approval from the Ethics Committee. The SAGER guidelines were followed according to the nature of the study. IRB number: Marmara University Faculty of Medicine Clinical Research Ethics Committee (Date: 07.05.2021/No: 09.2021.511) Clinical trial registration number: https://clinicaltrials.gov/, No: NCT05137574 (https://register.clinicaltrials.gov/prs/app/action/SelectProtocol?sid=S000BK3J&selectaction=Edit&uid=U0004KE3&ts=2&cx=-d2tci9)

Declaration on the use of artificial intelligence. The authors declare that no generative artificial intelligence was used in the writing of this manuscript.

Supplementary data

Supplementary data are available at DOI: 10.24875/CIRU.24000615. These data are provided by the corresponding author and published online for the benefit of the reader. The contents of supplementary data are the sole responsibility of the authors.

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