ORIGINAL ARTICLE

Respiratory monitoring during endoscopic procedures: efficacy and clinical significance of integrated pulmonary index, randomized controlled trial

Monitoreo respiratorio durante procedimientos endoscópicos: eficacia y significado clínico del índice pulmonar integrado, ensayo controlado aleatorizado

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Abstract

Objective: *In sedation practices, respiratory monitoring, particularly for endoscopic procedures, remains crucial due to the risk of respiratory complications. Despite standard monitoring recommendations, significant hypoventilation may occur, leading to adverse events. Integrated pulmonary index® (IPI) offers comprehensive respiratory status assessment, yet its utility in endoscopic sedation remains unclear.* **Methods:** *A prospective, double-blind, randomized controlled trial was conducted at Kartal City Hospital between July and September 2022. Patients aged 18-80 undergoing endoscopic procedures were randomized into standard monitoring (Group 1) or capnography with IPI monitoring (Group 2). Both groups received standard monitoring, whereas Group 2 additionally had capnography monitoring.* **Results:** *Of the 200 patients included, no significant differences were observed in demographics or procedure types between groups. Apnea duration was significantly lower in Group 2 (IPI group). Group 2 showed higher peripheral oxygen saturation (SpO_2) and IPI values at specific intervals compared to Group 1. However, the occurrence of apnea did not significantly differ between groups.* **Conclusion**: *While capnography with IPI monitoring showed advantages in reducing apnea duration and maintaining higher SpO_2 levels, these differences were not clinically significant. Capnography's role as an adjunct to standard monitoring in preventing respiratory complications during endoscopic procedures needs further evaluation, considering its cost implications.*

Keywords: *Sedation. Respiratory monitoring. Endoscopic procedures. Capnography. Integrated pulmonary index. Hypoxemia.*

Resumen

Objetivo: *En las prácticas de sedación, el monitoreo respiratorio, en especial para procedimientos endoscópicos, sigue siendo crucial debido al riesgo de complicaciones respiratorias. A pesar de seguir las recomendaciones de monitoreo estándar, puede ocurrir una hipoventilación significativa, lo que conlleva eventos adversos. El índice pulmonar integrado (IPI) ofrece una evaluación completa del estado respiratorio; sin embargo, su utilidad en la sedación endoscópica sigue siendo incierta.* **Métodos:** *Los pacientes de 18 a 80 años sometidos a procedimientos endoscópicos fueron asignados al azar para recibir monitoreo estándar (grupo 1) o monitoreo de capnografía con IPI (grupo 2). Ambos grupos recibieron monitoreo estándar, pero el grupo 2 tuvo además monitoreo de capnografía.* **Resultados:** *De los 200 pacientes incluidos, la duración de la apnea fue significativamente menor en el grupo 2 (IPI). El grupo 2 mostró valores más altos de SpO_2 y del IPI en intervalos específicos en comparación con el grupo 1. Sin embargo, la ocurrencia de apnea no difirió significativamente entre los grupos.*

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Conclusiones: *Aunque la capnografía con monitoreo IPI mostró ventajas en la reducción de la duración de la apnea y el mantenimiento de niveles más altos de SpO_2, las diferencias no fueron clínicamente significativas. El papel de la capnografía como complemento al monitoreo estándar en la prevención de complicaciones respiratorias durante los procedimientos endoscópicos requiere una evaluación adicional, considerando sus implicaciones económicas.*

Palabras clave: *Sedación. Monitoreo respiratorio. Procedimientos endoscópicos. Capnografía. Índice pulmonar integrado. Hipoxemia.*

Introduction

In sedation practices, monitoring, particularly respiratory monitoring, is crucial for anesthesiologists. Even with moderate sedation targeted for endoscopic procedures, patients remain susceptible to drug-induced airway obstruction, aspiration, respiratory depression, and progression to deep sedation. Current guidelines recommend standard monitoring of heart rate (HR), non-invasive blood pressure (NBP), and peripheral oxygen saturation (SpO_2) during procedures requiring sedation, such as endoscopy. However, significant alveolar hypoventilation can occur even with normal SpO_2 values measured by pulse oximetry. Neither clinical observation nor pulse oximetry can detect hypoventilation, apnea, hypercarbia, and consequent early signs of acidosis, arrhythmias, and myocardial depression[1]. In addition, it has been demonstrated that apnea and respiratory changes often occur well before significant hypoxemia[2,3]. Therefore, early detection of desaturations accelerates interventions to prevent prolonged hypoxemia. Integrated pulmonary index® (IPI), designed for respiratory monitoring and early detection of desaturation, automatically calculates using four components (1: End-tidal carbon dioxide [$EtCO_2$], 2: Respiratory rate [RR], 3: SpO_2, and 4: HR), providing a summary of the patient's ventilation and oxygenation status based on a single parameter. IPI values are scored between 1 and 10. Values between 7 and 10 reflect stable respiratory parameters, whereas values below 7 indicate the need for respiratory intervention[4].

The primary hypothesis of this study is to investigate the necessity of measuring IPI for monitoring respiratory status in patients undergoing endoscopic procedures under deep sedation and to evaluate whether IPI monitoring helps reduce hypoxemic events compared to standard monitoring. The secondary hypothesis involves measures to address complications such as hypotension, bradycardia, and restoring normoventilation.

Methods

This study was planned as a prospective, double-blind, randomized controlled trial and was approved by the local ethics committee (Kartal Dr. Lütfi Kirdar City Hospital Clinical Research Ethics Committee; decision no. 2022/514/228/17). It was designed according to the principles outlined in the Helsinki Declaration and was conducted at Kartal City Hospital between July and September 2022. Written informed consent was obtained from all patients for participation in the study.

The study aimed to include patients aged 18-80 undergoing diagnostic sedation for endoscopic procedures (endoscopy and colonoscopy), of both genders, classified as American Society of Anesthesiologists (ASA) class I-III. Patients with significant cardiopulmonary comorbidities (uncontrolled hypertension, chest pain, advanced heart failure, etc.), ASA 4 and above, propofol allergy, and those aged under 18 or over 80 were excluded from the study. Patients with procedure abandonment, refusal of sedation, or device malfunction were also excluded. The Consolidated Standards of Reporting Trials flow diagram was used for patient enrollment (Fig. 1).

Intervention and anesthesia regimen

After pre-operative evaluation, patients were randomly assigned to either the standard monitoring group (Group 1) or the capnography monitoring group with IPI (Capnostream®/Covidien) (Group 2) according to a randomization table generated by a researcher who did not participate in the study. Each group was assigned a random code of 0 or 1, and these codes were placed in sealed envelopes. Patient monitoring commenced based on the code selected from the envelope. Both groups received standard monitoring, including clinical observation, pulse oximetry, NBP, and HR monitoring. In the IPI group, capnographic data were recorded for the evaluation of patients'

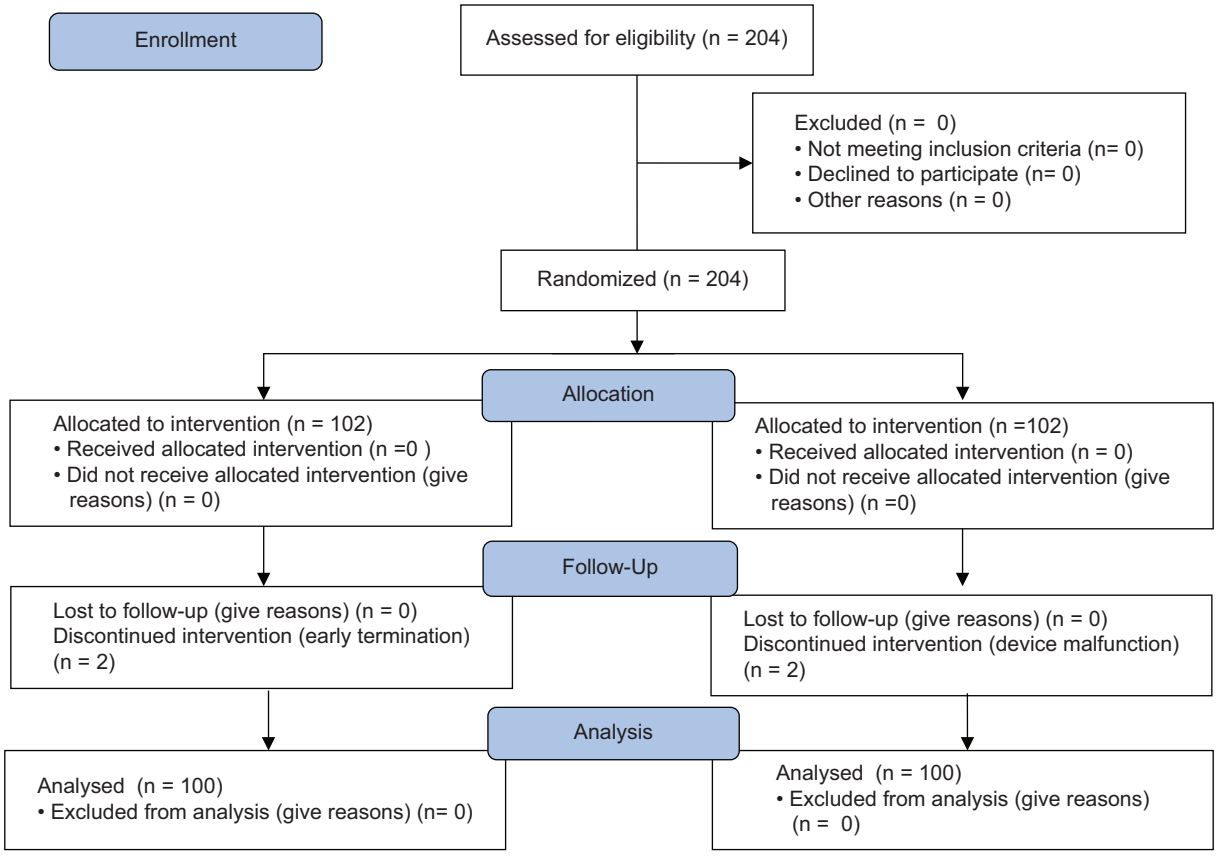

Figure 1. *Consort flow diagram.*

respiratory status. In the standard group, capnographic data with IPI were continuously recorded, but an opaque black cover was placed over the capnography screen. All data were recorded by an independent observer not involved in endoscopic and sedation procedures.

In both groups, a special apparatus with a nasal cannula was used to continuously sample CO_2 content during both inhalation and exhalation (Smart CapnoLine Plus O_2 Microstream; Oridion Medical, Needham, MA, United States) (Fig. 2). The sampling line was connected to the capnography monitor, and sedation was administered with standard doses of anesthetic drugs before starting the endoscopic procedure, with an oxygen flow of 4 L/min. Sedation was achieved using standard doses of anesthetic drugs (2 mg midazolam, 1 mg/kg propofol, and 50 mcg fentanyl). Lower initial doses of propofol were administered to elderly patients or those with pre-existing serious comorbidities. After the initial dose of sedatives, additional doses of propofol (0.5 mg/kg) were administered as needed to achieve an adequate sedation level. The depth of sedation was assessed using the Observer Assessment of Alertness/Sedation Scale (OAA/S), and a target OAA/S score of 3 was maintained. Anesthesia depth was also measured using bispectral index (BIS), and titration of anesthetic drugs was performed to maintain BIS values between 60 and 80.

Patient's vital signs, including HR, NBP, SpO_2, IPI, RR, $EtCO_2$, BIS, and OAA/S scores, were recorded at the start of the procedure, 1 min after induction, and then at 3, 5 min intervals during the procedure, and post-procedure. A capnographic criterion for apnea was defined as the absence of $EtCO_2$ for 10 s. After the completion of the study, a retrospective analysis was performed in Group 1 to determine the number of apneic episodes (> 10 s) detected by capnographic monitoring (including IPI).

In Group 1, interventions for hypoxic events (defined as a decrease in SpO_2 > 5% or hypoventilation < 5 breaths/min) were based on clinical observation and SpO_2 evaluation. In Group 2, interventions were initiated when $EtCO_2$ remained at 0 mmHg for more than 10 s or when IPI was < 7, and the capnography

IPI	Patient Status
10	Normal
8-9	Within normal range
7	Close to normal range; requires attention
5-6	Requires attention and may require intervention
3-4	Requires intervention
1-2	Requires immediate intervention

Figure 2. *Apnea condition, patient status, and integrated pulmonary index values.*

monitor provided both auditory and visual alarms for apnea. Interventions to improve ventilation and/or oxygenation included cessation or reduction of sedatives, increasing oxygen support, stimulating the patient, chin lift, or jaw thrust maneuvers.

At the end of the procedure, in addition to respiratory complications, other complications such as hypotension, bradycardia, bleeding, aspiration, etc., were recorded.

After completion of the endoscopic procedure, monitor connections were discontinued provided that patients could provide a meaningful verbal response and hemodynamic parameters were stable. The Modified Aldrete Score (MAS) was used for post-procedure recovery assessment. Patients with MAS > 9 were transferred to the post-anesthesia care unit. Subsequently, patients were transferred to the recovery room and discharged to the inpatient ward from the endoscopy unit.

Study outcomes and measurement

The primary outcome of the study was defined as a decrease of at least 5% in SpO_2 or apnea lasting ≥ 10 s. The secondary outcome included hypotension (systolic blood pressure < 90 mmHg and/or a decrease of ≥ 25% from baseline), bradycardia (HR ≤ 60), and interventions to restore normoventilation.

The device manufacturer had no role in the design, data collection, data analysis, or manuscript preparation of this study.

Statistical analyses

Statistical analyses were performed using the Statistical Package for the Social Sciences version 25. The data of the study were summarized using descriptive statistical methods (mean, frequency, and percentage). The Shapiro-Wilk test was used to determine whether continuous variables followed a normal distribution. Fisher's exact test was applied to evaluate independence between categorical variables in 2 × 2 contingency tables. Mann-Whitney test was employed to compare non-normally distributed continuous variable data between the two groups to investigate differences. The Wilcoxon signed-rank test was used for the difference test between dependent groups. A significance level of 0.05 was considered for all tests.

G*Power Version 3.1.9.7 was used for sample size calculation. The mean decrease in oxygen saturation during interventional endoscopy under sedation was calculated as 6 ± 4.5% based on a previous study[5]. To detect a 50% reduction in this parameter with additional IPI assessment, 81 patients were required for each group (using the Mann-Whitney test with a two-sided significance level of $p < 0.01$ and 95% power). A total of 195 patients were planned to be enrolled, considering a 20% dropout rate.

Results

A total of 204 patients were planned to be enrolled and randomized into groups. However, due to premature termination of endoscopic procedures in Group 1 and device malfunction in two patients in Group 2, a total of 200 patients were included in the study, with 100 patients in each group. Of these patients, 109 (54.5%) were female, and 91 (45.5%) were male. The mean age of all patients was 54.98 years. A total of 62 patients (31%) underwent gastroscopy, 76 patients (38%) underwent colonoscopy, and 62 patients (31%) underwent both gastroscopy and colonoscopy.

Statistical analysis between groups showed no significant differences in age, gender, body mass index, chronic disease, ASA score, or type of procedure ($p > 0.05$). There were also no significant differences between groups in the need for additional propofol dose and intervention requirement ($p > 0.05$) (Table 1).

Since there were 100 patients in each group, the frequency given in table 1 is also the percentage. Among the variables, only the duration of apnea was statistically significant, with a $p < 0.05$. The duration

of apnea (seconds) in Group 2 was significantly lower than in Group 1 (p: 0.000).

The mean SpO_2 values at 3 and 5 min in Group 2 were significantly higher than those in Group 1 (p: 0.017, p: 0.050). Similarly, the mean IPI value at 3 min in Group 2 was significantly higher than that in Group 1 (p: 0.00) (Table 2).

There was no statistically significant difference in HR and NBP values between groups ($p > 0.05$) (Table 2).

Although the percentage of patients with apnea duration of 10 s or more was higher in Group 1 (52.3%) compared to Group 2 (47.7%), this difference was not statistically significant (p: 0.229) (Table 3).

There is no difference between groups in terms of the average decreased percentage of SpO_2 after induction compared to baseline. However, regarding the percentage decreases after baseline at 3 and 5 min, the average SpO_2 decrease percentage in Group 1 is significantly higher than that in Group 2 ($p < 0.05$) (Table 4).

There is a significant difference between the groups in terms of the number of patients with decreases in SpO_2 between baseline and 3 min, categorized as < 5% or 5% or more. There have been higher rates of 5% or higher SpO_2 decreases in Group 1 (p:0.000) (Table 5).

Spearman Rho correlation coefficients between SpO_2 and IPI differences at baseline, 3 min, and 5 min are provided. It is understood that the decrease in IPI compared to SpO_2 is considerably higher from baseline to induction, the difference closes after 3 min, and at 5 min, the decrease in SpO_2 exceeds that in IPI (Fig. 3).

Primer outcome measures

Hypoxemia (SpO_2 decrease percentage) occurred more frequently in Group 1 compared to Group 2. Apnea was detected in 62 patients in Group 2. However, hypoxemia developed in only 20 of these patients.

Secondary outcome measures

There was no significant difference between the two groups in terms of intervention requirement (p: 0.752), hypotension, and bradycardia. No serious adverse effects, such as orotracheal intubation, cardiopulmonary resuscitation, or death, were observed in either group.

Table 1. Demographic data and test results for differences between variables

	Group		
Variables	**IPI (Group 2)**	**SM (Group 1)**	**p**
Age, median (SD)	55.54 ± 1.23	54.43 ± 1.19	0.463[1]
Gender			
Female	55	54	
Male	45	46	
BMI (SD)	23.86 ± 3.5	23.76 ± 3.32	0.823[1]
Chronic disease			
+	16	14	0.575[2]
–	84	86	
ASA score			
1	18	17	
2	64	63	
3	18	20	
Type of procedure			
G	30	28	0.938[3]
C	38	40	
G + C	32	32	
Additional propofol			
–	40	39	0.280[2]
+	60	61	
Intervention requirement			
–	40	40	0.752[3]
+	60	60	
Duration of apnea, sec, mean (SD)	18.26 ± 1.15	28.16 ± 1.59	0.000[3]

[1]Mann–Whitney.
[2]Fisher's exact test.
[3]χ^2 test.
IPI: integrated pulmonary index; SM: standard monitoring; BMI: body mass index; SD: standard deviation; G: gastroscopy; C: colonoscopy.

Discussion

The use of capnography is a standard part of monitoring in patients undergoing general anesthesia. However, its role is being investigated in procedures requiring sedation. In this study, we aimed to demonstrate whether early interventions with capnography monitoring could be beneficial in preventing sedation-related hypoxemia. We found that there was no significant difference between the two groups in terms of the occurrence of apnea and interventions. However, capnography was superior to standard pulse oximetry in shortening the apnea duration.

The similarity in the average reduction of oxygen saturation between the IPI group and the control group led to the conclusion that there is no discernible

Table 2. Comparison of hemodynamic parameters between groups

Group	Basal SpO_2	1st min SpO_2	3rd min SpO_2	5th min SpO_2	Post-proc SpO_2	Basal IPI	1st min IPI	3rd min IPI	5th min IPI	Post-proc IPI
IPI (Group 2)										
Mean	98.74	96.39	96.63	96.71	97.04	9.59	6.21	7.27	7.64	8.88
SD	0.16	0.26	0.23	0.23	0.19	0.05	0.19	0.15	0.14	0.05
SM (Group 1)										
Mean	98.84	96.14	95.60	95.94	97.00	9.59	6.02	6.43	7.57	8.87
SD	0.17	0.26	0.28	0.25	0.19	0.05	0.19	0.17	0.14	0.06
p	0.891	0.507	**0.017**	**0.050**	0.874	1.000	0.425	**0.000**	0.711	0.986

Group	Basal HR	1st min HR	3rd min HR	5th min HR	Post-proc HR	Basal NBP	1st min NBP	3rd min NBP	5th min NBP	Post-proc NBP
IPI (Group 2)										
Mean	79.46	79.05	78.96	78.16	93.96	93.07	91.97	91.34	90.45	90.01
SD	1.40	1.31	1.37	1.31	1.69	1.66	1.62	1.42	1.27	0.22
SM (Group 1)										
Mean	79.48	79.03	78.94	78.13	93.65	92.42	91.62	90.93	90.25	90.01
SD	1.39	1.31	1.37	1.31	1.66	1.58	1.59	1.37	1.24	0.22
p	0.798	0.984	0.982	0.973	0.972	0.886	0.811	0.873	0.906	0.960

IPI: integrated pulmonary index; SM: standard monitoring; SD: standard deviation; post-proc: post-procedure; HR: heart rate; NBP: non-invasive blood pressure; Mann–Whitney U test.

Table 3. Apnea status between groups

	Group		
Apnea status	**IPI (Group 2)**	**SM (Group 1)**	**p**
No apnea observed or apnea duration < 10 s			
n	38	32	0.229
Percentage	54.3	45.7	
10 s or more apnea duration			
n	62	68	
Percentage	47.7	52.3	

IPI: integrated pulmonary index; SM: standard monitoring. Fisher's exact test.

Table 4. Difference in mean SpO_2 decrease percentages between groups compared to baseline

	Group		
SpO2 decrease interval	**IPI (Group 2)**	**SM (Group 1)**	**p**
Mean percentage decrease in SpO_2 from baseline to 1 min	2.38	2.63	0.408
Mean percentage decrease in SpO_2 from baseline to 3 min	2.14	3.18	0.017
Mean percentage decrease in SpO_2 from baseline to 5 min	2.06	2.84	0.050

IPI: integrated pulmonary index; SM: standard monitoring.

advantage in utilizing the IPI index for interventional endoscopic procedures. However, the use of the IPI did not demonstrate any additional clinical benefit. Our study did not detect significant complications such as the need for mechanical ventilation, cardiopulmonary resuscitation, or death. Still, it was evaluated based on the results of larger studies utilizing capnography[6,7].

European guidelines recommend additional capnography monitoring for prolonged procedures or deep sedation[8,9]. Various studies have shown that supplemental capnography monitoring in addition to standard monitoring aids in preventing desaturation during standard endoscopic procedures such as esophagogastroduodenoscopy and colonoscopy[6,10,11]. Garah et al. found in a study conducted on 109 pediatric patients undergoing upper endoscopy under sedation that the IPI alerted to all apneic episodes and hypoxic events, whereas pulse oximetry only detected hypoxic episodes[4]. However, these results contradict our findings. No difference in the occurrence of apnea was found between the two groups.

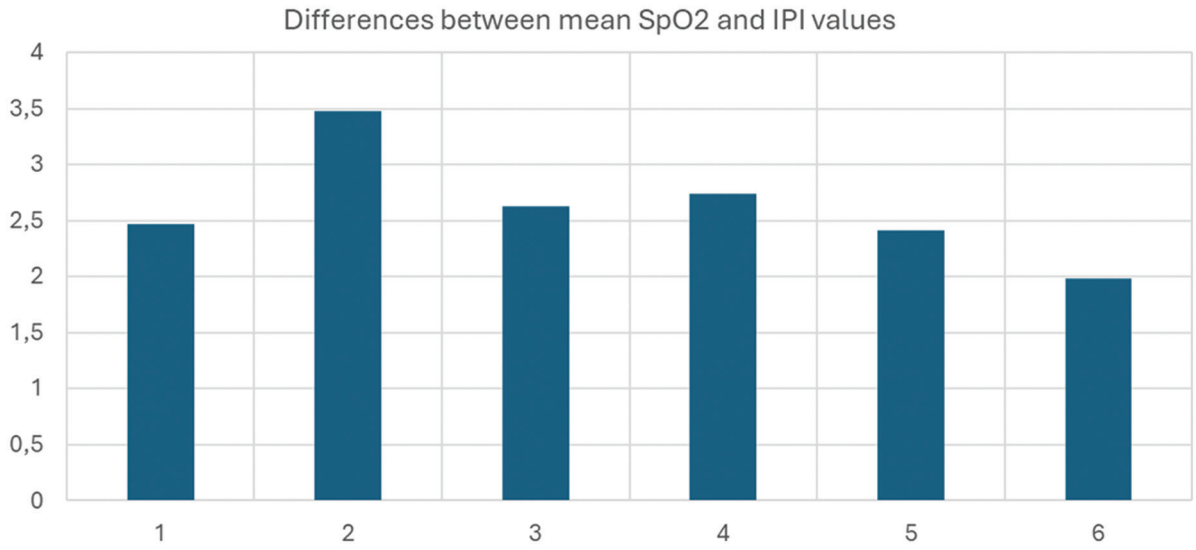

Figure 3. *Spearman rho correlation coefficients between SpO_2 and integrated pulmonary index values. (1) IPI baseline to 5th min, (2) SpO_2 baseline to 5th min, (3) IPI baseline to 3rd min, (4) SpO_2 baseline to 3rd min, (5) IPI baseline to 1st min, and (6) SpO_2 baseline to 1st min. IPI: integrated pulmonary index.*

Table 5. Differences in SpO_2 decrease percentages between groups according to period

Group	Rate of decrease in SpO_2 from baseline to induction		p
	< 5%	5% or more	
IPI (n)	89	11	0.414
SM (n)	87	13	
Group	**Rate of decrease in SpO_2 from baseline to 3 min**		
	< 5%	**5% or more**	
IPI (n)	98	2	0.000
SM (n)	83	17	
Group	**Rate of decrease in SpO_2 from baseline to 5 min**		
	< 5%	**5% or more**	
IPI (n)	93	7	0.083
SM (n)	86	14	

IPI: integrated pulmonary index; SM: standard monitoring.

Berkenstadt et al. observed 113 events requiring attention in patients undergoing moderate sedation during colonoscopy, but they noted only limited concordance between irregular respiratory parameters and the IPI[12]. Riphaus et al. compared the control group with the IPI group in a study involving 170 endoscopy patients undergoing deep sedation. They noted that IPI did not provide a significant clinical advantage. They noted no significant difference in the average maximum decrease in SpO_2 and hypoxic events between the groups but found that the IPI was effective in reducing the frequency of apneic episodes[8]. In our study, apnea was detected in 62 patients in the IPI group, but hypoxemia developed in only 20 of these patients. In addition, a significant correlation was found only between SpO_2 decrease at 3 min and the IPI, with no differences observed at other time intervals.

Mehta et al. and Qadeer et al. defined respiratory disturbances as a reduction of > 75% in the amplitude of respiratory waves lasting ≥ 5 s in their studies involving patients undergoing endoscopic retrograde cholangiopancreatography and endoscopic ultrasound[13,14]. In both studies, there was no significant difference in terms of respiratory disturbances between the control group and the capnography group. Furthermore, no association was observed between respiratory disorders and hypoxic events, which our study also supports.

In our study, contrary to a study by Vargo et al. that showed the inadequacy of clinical observation for assessing ventilation, abnormal ventilation and apnea observed clinically in the standard monitoring group were similar to those in the IPI group[2]. Only the duration of apnea differed between the two groups (IPI: 18.26 s;

SI: 28.16 s). However, this difference did not yield a clinically significant result. There were also no significant differences in interventions between the two groups.

In addition, while apnea was detected in 62% of patients in the IPI group, oxygen desaturation occurred in only 20% of these patients. In the literature, the main mechanism of hypoxic events is described as a series of events starting with apnea and leading to hypoxemia[15,16]. However, when additional oxygen is present and consequently an increase in basal oxygen partial pressure, only some impaired ventilation episodes result in hypoxemia. While these episodes are detected by the IPI, pulse oximetry measures hemoglobin oxygenation and may not adequately reflect the patient's ventilation status. Furthermore, inadequate respiratory activity or complete absence of chest movement, signs of apnea, are often not detected during standard monitoring. However, measures can be taken when pulse oximetry warns of a subsequent decrease in SpO_2 due to hypoxemia. Peveling-Oberhag et al. found that blind capnographic measurements in the standard monitoring group had an average delay of more than a minute in detecting apnea and hypoxemia, and early application of interventions (including jaw lift/chin thrust maneuvers) in the capnography group led to a decrease in hypoxemic events[17]. However, neither our study nor any previous study reports that additional capnography monitoring during endoscopic sedation prevents side effects such as death or serious morbidity[18]. In our study, neither serious side effects nor deaths occurred. In addition, there is a significant increase in costs associated with increased capnographic monitoring. However, no controlled trial has demonstrated a mortality benefit, even with the widespread use of pulse oximetry. In our study, no life-threatening conditions requiring intervention emerged, and there was no notable difference in the need for intervention between the groups.

Berkenstadt et al. found no difference in RR, SpO_2, and HR between groups when they grouped patients according to IPI values. However, high $ETCO_2$ values were obtained in the high IPI group[12]. In our study, there was no difference in hemodynamic parameters between the two groups.

Our study has various limitations. Hypoxemic events were observed before clinically significant results emerged, and we did not have any patients with severe hypoxemia (SpO_2 < 85%). However, it is unclear whether severe hypoxemia can serve as a sufficient cause for sedation-related complications. In addition, routine oxygen supplementation may lead to high SpO_2 measurements, masking hypoventilation, but its use is recommended during endoscopy due to guidelines advocating its routine use.

Conclusion

Although capnography appears to reduce the number and duration of hypoxic events during endoscopic procedures, the results are not clinically significant. Capnography can significantly contribute to the prevention of respiratory complications; however, it should be noted that the presence of a normal capnogram does not guarantee adequate oxygenation. Therefore, while capnography cannot replace standard patient monitoring and clinical observation, it can be accepted as a useful adjunct. However, due to limited clinical benefits and increased costs associated with the use of capnography, we do not consider capnography necessary during endoscopic procedures.

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Conflicts of interest

The authors declare that they have 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.

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

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