

Value of integrated pulmonary index monitoring for the detection of adverse respiratory events in patients undergoing sedation for gastrointestinal system endoscopy

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Abstract

Objective: To determine if the integrated pulmonary index detects changes in ventilation status early in patients undergoing gastrointestinal endoscopy under sedation, and to determine the risk factors affecting hypoxia.

Method: The retrospective study was conducted at the endoscopy unit of a tertiary university hospital in Turkey and comprised data between October 2018 and December 2019 related to patients of either gender aged >18 years who were assessed as American Society of Anaesthesiologists grade I-III and underwent elective lower and upper gastrointestinal endoscopy. Monitoring was done with capnography in addition to standard procedures. Data was analysed using SPSS 23.

Results: Of the 154 patients, 94(%) were females and 60(%) were males. The overall mean age was 50.88±11.8 years (range: 20-70 years). Mean time under anaesthesia was 23.58±4.91 minutes and mean endoscopy time was 21.73±5.06 minutes. During the procedure, hypoxia was observed in 42(27.3%) patients, severe hypoxia in 23(14.9%) and apnoea in 70(45.5%). Mean time between apnoea and hypoxia was 12.59±7.99 seconds, between apnoea and serious hypoxia 21.07±17.64 seconds, between integrated pulmonary index score 1 and hypoxia 12.91±8.17 sec, between integrated pulmonary index score 1 and serious hypoxia 21.59±14.13 seconds, between integrated pulmonary index score <7 and hypoxia 19.63±8.89 seconds, between integrated pulmonary index score <7 and serious hypoxia 28.39±12.66 seconds, between end-tidal carbon dioxide and hypoxia 12.95±8.33 seconds, and between end-tidal carbon dioxide and serious hypoxia 21.29±7.55 seconds. With integrated pulmonary index score 1, sensitivity value for predicting hypoxia and severe hypoxia was 88.1% and 95.7%, respectively, and specificity was 67% and 60.3%, respectively. With integrated pulmonary index score <7, the corresponding values were 100%, 100%, 42% and 64.1%, respectively.

Conclusion: Capnographic monitoring, especially the follow-up integrated pulmonary index score, was found to be valuable and reliable in terms of finding both time and accuracy of the risk factor in the diagnosis of respiratory events.

Key Words: Endoscopy, Hypoxia, Index monitoring, Pulmonary
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Introduction

Endoscopic procedures of the gastrointestinal tract (GIT) are common diagnostic techniques for the investigation and monitoring of GIT pathologies. These endoscopic procedures are usually performed under sedation with the help of anaesthetic agents. Cardiovascular and respiratory systems are where the most important side effects of anaesthetic drugs are observed. In sedated patients, respiratory depression and airway obstruction

secondary to medications are major causes of morbidity and mortality.^{1,2} The main anaesthetic agent used for sedation is propofol. Cardiopulmonary side effects of propofol are reported as being oxygen saturation <90% in 57%, short-term masked ventilation requirement in 0.4% and requirement for endotracheal intubation in 0.09% of patients.³

In non-operating rooms (ORs), such as endoscopy units, basic patient safety requirements should be established. International guidelines recommend pulse oximetry, non-invasive blood pressure (BP) measurement and clinical observation to ensure patient safety. Electrocardiography (ECG) is suggested in patients with serious cardiac disease, heart failure and patients with arrhythmia. It is known that apnoea episodes leading to hypoxia cannot be detected through standard monitoring. Endoscopy guidelines from Europe and the United States suggest capnographic monitoring, especially in patients who

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undergo deep sedation or if the sedation is expected to last for an extended period of time.¹ The Turkish Society of Anaesthesiology and Reanimation's non-OR anaesthesia guideline recommends using end-tidal carbon dioxide (EtCO₂) monitoring not only in situations of moderate and deep sedation, but also in cases of light sedation.⁴

Peripheral oxygen saturation (SpO₂), EtCO₂, respiratory rate (RR) and heart rate (HR) are frequently used to evaluate the patient's respiratory functions. The interpretation of data obtained from these measurements is an important problem, particularly for healthcare practitioners who are unfamiliar with respiratory monitoring.⁵ The integrated pulmonary index (IPI) is calculated by computationally integrating SpO₂, EtCO₂, RR and HR measurements. This index may be constantly monitored on the patient monitor in numerical or wave form. The IPI score is evaluated on a scale from 1 (respiratory failure) to 10 (normal breathing). IPI is used in procedures occurring under sedation, like gastroscopy, colonoscopy, cardioversion, tooth extraction, etc., intensive care units (ICUs), like adjustment of mechanical ventilator parameters, evaluation of ventilator/patient compliance, follow-up of weaning process, etc., and in the postoperative follow-up of patients undergoing coronary artery bypass graft (CABG) surgery, like evaluation of respiratory problems, follow-up of weaning processes, etc.^{6,7}

The current study was planned to determine if the IPI score detects changes in ventilation status early in patients undergoing gastrointestinal endoscopy under sedation, and to determine the risk factors affecting hypoxia.

Materials and Methods

The retrospective study was conducted at the endoscopy unit of a tertiary university hospital in Turkey after approval from the ethics review committee of Samsun Training and Research Hospital, Turkey, and comprised data between October 2018 and December 2019 related to patients of either gender aged >18 years who were assessed as American Society of Anaesthesiologists (ASA)⁸ grade I-III and underwent elective lower and upper gastrointestinal endoscopy. Monitoring was done with capnography in addition to standard procedures, like ECG, non-invasive BP and pulse oximetry. Data of patients was excluded if capnography information was missing, those aged <18 years, ASA IV-V, emergency endoscopic intervention, like GI bleeding, trauma etc., pre-procedural SpO₂ <90%, systolic blood pressure (SBP) <90mmHg or HR <50bpm.

The sample size was calculated using G*Power 3.1 (G*Power®, version 3.1.9.2; Institute for Experimental Psychology in Dusseldorf, Germany).⁹ Post-hoc power analysis was performed considering the analyses on the relationship between the IPI value of the subjects and the occurrence of hypoxia.¹⁰⁻¹² The effect size was calculated as $W(\Phi)=1.70$ (large) from the contingency tables of the relevant variables. It was seen that the power level calculated after the study with an alpha significance level of 0.05 was above 95%.

As per the study protocol, all patients in the endoscopy unit were routinely administered 2 L/min oxygen during the procedure. Patients were premedicated with 2 mg midazolam 5 minutes before the procedure. A bolus of 1-1.3 mg/kg propofol was administered before the procedure. During the procedure, propofol 10-30 mg was administered in repeated doses, as required according to the Ramsay sedation scale (RSS).¹³

SpO₂ <92% on pulse oximetry lasting over 15 seconds was defined as hypoxia, while SpO₂ <85% was defined as serious hypoxia. Also recorded were IPI=1, IPI<7, EtCO₂=0, apnoea, tachypnoea (RR >20/m), tachycardia (HR >120bpm) and bradycardia (HR <50bpm).

IPI score^{6,7} was measured using an IPI device (Smart Capnography, Algorithms-MicrostreamTechnology, Medtronic Limited, United Kingdom). Based on information acquired from the patients and stored on the capnography disc memory, data was retrieved for the number of hypoxic events, number of serious hypoxia events, apnoea episodes (flat line on capnography lasting >15 seconds with no respiratory activity), events involving hypoxia or serious hypoxia along with apnoea episode, as well as time from apnoea to hypoxia or serious hypoxia, and time between IPI=1, IPI<7, EtCO₂=0 and hypoxia or serious hypoxia episode.

If the EtCO₂ dropped to 0 mmHg for >10 seconds or hypoventilation (<5 breaths/minute) occurred, the capnography monitor gave an acoustic and visual apnoea alarm. Interventions to restore ventilation and/or oxygenation were immediately initiated by the person performing sedation in escalating order as: patient stimulation, interruption or reduction of sedatives, chin lift or jaw thrust manoeuvre, and bag-valve-mask ventilation.

Data was analysed using SPSS 23. Normality of data distribution was evaluated using Shapiro-Wilk test, and was found to be normally distributed. Data was reported using mean ± standard deviation, and frequencies with percentages, as appropriate. Student t test, Fisher's exact

and Pearson chi-square tests were used for inter-group comparison. Repeated analysis of variance (ANOVA) test was used to compare repeated observations. In addition to clinical characteristics, laboratory and treatment methods were first analysed using univariate logistic regression. Variables found to be significant were then analysed using the stepwise multivariate logistic regression. $P < 0.05$ was considered statistically significant.

Results

Of the 154 patients, 94(61%) were females and 60(39%) were males. The overall mean age was 50.88 ± 11.8 years (range: 20-70 years). Mean time under anaesthesia was 23.58 ± 4.91 minutes and mean endoscopy time was 21.73 ± 5.06 minutes (Table 1).

Table-1: Demographic and clinical characteristics.

Variables	n(%)/mean \pm sd
Age (years)	50.88 \pm 11.79
BMI (kg/m ²)	28.06 \pm 4.25
Gender (n,%)	
Male	60 (39.0)
Female	94 (61.0)
ASA (n,%)	
I	35 (22.7)
II	100 (64.9)
III	19 (12.4)
Morbidity (n,%)	
Yes	119 (77.3)
No	35 (22.7)
Anaesthesia time (min.)	23.58 \pm 4.91
Endoscopy time (min.)	21.73 \pm 5.06

ASA: American Society of Anaesthesiologists, BMI: Body mass index, Min: Minute, SD: Standard deviation.

During the procedure, hypoxia was observed in 42(27.3%) patients, severe hypoxia in 23(14.9%) and apnoea in 70(45.5%). Mean time between apnoea and hypoxia was 12.59 ± 7.99 seconds, between apnoea and serious hypoxia 21.07 ± 17.64 seconds, between IPI=1 and hypoxia 12.91 ± 8.17 sec, between IPI=1 and serious hypoxia 21.59 ± 14.13 seconds, between IPI<7 and hypoxia 19.63 ± 8.89 seconds, between IPI<7 and serious hypoxia 28.39 ± 12.66 seconds, between EtCO₂ and hypoxia 12.95 ± 8.33 seconds, and between EtCO₂ and serious hypoxia 21.29 ± 7.55 seconds (Table 2).

With IPI=1, sensitivity value for predicting hypoxia and severe hypoxia was 88.1% and 95.7%, respectively, and specificity was 67% and 60.3%, respectively. With IPI<7, the corresponding values were 100%, 100%, 42% and 64.1%, respectively (Table 3).

Table-2: Changes in respiratory and IPI values that occurred during the procedure.

Variables	mean \pm sd
Apnoea episode (n)	2.16 \pm 1.48
Apnoea-hypoxia-related event (n)	1.09 \pm 0.83
Apnoea-severe hypoxia-related event (n)	1.07 \pm 0.7
Time between apnoea and hypoxia (min)	13.59 \pm 7.99
Time between apnoea and severe hypoxia (min)	21.07 \pm 17.64
IPI=1 number of events (n)	2.32 \pm 1.67
IPI=1-Hypoxia-related event (n)	1.31 \pm 0.82
IPI=1-time between hypoxia (min)	12.91 \pm 8.17
IPI=1-time between severe hypoxia (min)	21.59 \pm 14.13
IPI<7 number of events (n)	5.78 \pm 3.65
IPI<7-Hypoxia-related event (n)	2.3 \pm 1.87
IPI<7-Severe hypoxia-related event (n)	1.68 \pm 1.55
IPI<7-time between hypoxia (min)	19.63 \pm 8.89
IPI<7-time between severe hypoxia (min)	28.39 \pm 12.66
EtCO ₂ =0 number of events (n)	1.77 \pm 1.38
EtCO ₂ =0 Hypoxia-related event (n)	1.03 \pm 0.78
EtCO ₂ =0 Severe hypoxia-related event (n)	1 \pm 0.58
EtCO ₂ =0 time between hypoxia (min)	12.95 \pm 8.33
EtCO ₂ =0 time between severe hypoxia (min)	21.29 \pm 17.55
Number of tachypnoeic events (n)	5.92 \pm 3.45
Tachypnoea-Hypoxia-related event (n)	1.11 \pm 1.37
Tachypnoea-Severe hypoxia-related event (n)	0.48 \pm 0.51
Number of tachycardia events (n)	1.75 \pm 1.24
Tachycardia-hypoxia-related event (n)	0.33 \pm 0.58
Tachycardia-severe hypoxia-related event (n)	0.5 \pm 0.71
Number of bradycardia events (n)	3 \pm 1.73
Bradycardia-hypoxia related event (n)	..
Bradycardia-severe hypoxia related event (n)	..

EtCO₂: End-tidal carbon dioxide, IPI: Integrated pulmonary index, Min: Minute, SD: Standard deviation.

Table-3: Hypoxia/severe hypoxia and sensitivity and specificity.

Parameters	Hypoxia events		Severe hypoxia events	
	Sensitivity	Specificity	Sensitivity	Specificity
IPI=1	88.1%	67.0%	95.7%	60.3%
IPI<7	100.0%	42.0%	100.0%	64.1%
EtCO ₂	66.7%	73.2%	65.2%	67.2%
Apnoea	83.3%	68.8%	78.3%	60.3%
Tachypnoea	97.6%	11.6%	95.7%	9.9%
Tachycardia	7.1%	88.4%	8.7%	89.3%
Bradycardia	0	97.3%	0	97.7%
Hypocapnia	100.0%	1.8%	100.0%	1.5%
Hypercapnia	4.8%	99.1%	4.3%	98.5%

EtCO₂: End tidal carbodioxide, IPI: Integrated Pulmonary Index

Age and time under anaesthesia values were not significantly different between hypoxia and serious hypoxia patients, while body mass index (BMI) in those with serious hypoxia was higher compared to those who had hypoxia ($p=0.048$). In both patients with hypoxia and serious hypoxia, IPI=1 ($p < 0.001$), IPI<7 ($p < 0.001$), apnoea

Table-4: Relation of IPI score and basic parameters with hypoxia and severe hypoxia.

*	Hypoxia			Severe hypoxia		
	Yes n(%) / mean±sd	No n(%) / mean±sd	P	Yes n(%) / mean±sd	No n(%) / mean±sd	P
Age (years)	49.07±10.82	51.55±12.1	0.246	47.74±9.85	51.43±12.04	0.167
BMI (kg/m ²)	27.19±4.08	28.39±4.29	0.12	26.44±4.6	28.35±4.14	0.048
Anaesthesia time (min)	24.79±4.99	23.13±4.82	0.063	24.52±5.71	23.42±4.76	0.322
IPI=1	37 (88.1)	37 (33.0)	<0.001	22 (95.7)	52 (39.7)	<0.001
IPI<7	42 (100.0)	65 (58.0)	<0.001	23 (100.0)	84 (64.1)	<0.001
EtCO ₂ =0	28 (66.7)	30 (26.8)	<0.001	15 (62.5)	43 (32.8)	0.003
Has apnoea developed?	35 (83.3)	35 (31.3)	<0.001	18 (78.3)	52 (39.7)	0.001
Has tachypnoea developed?	41 (97.6)	99 (88.4)	0.114	22 (95.7)	118 (90.1)	0.083
Tachycardia	3 (7.1)	13 (11.6)	0.559	2 (8.7)	14 (10.7)	0.537
Bradycardia	0 (0)	3 (2.7)	0.563	0 (0)	3 (2.3)	0.356
Hypocapnia	42 (100.0)	110 (98.2)	0.999	23 (100.0)	129 (98.5)	0.815
Hypercapnia	2 (4.8)	1 (0.9)	0.181	1 (4.3)	2 (1.5)	0.367

BMI: Body mass index, EtCO₂: End-tidal carbon dioxide, IPI: Integrated pulmonary index, Min: Minute, SD: Standard deviation. P value was obtained from Student t test or Pearson Chi Square test.

Table-5: Multivariate analysis of the relationship of hypoxia and severe hypoxia with significant IPI parameters.

	Hypoxia		Severe hypoxia	
	Odds Ratio (95% CI)	P	Odds Ratio (95% CI)	P
IPI=1	10.91 (2.06-57.66)	0.005	73.89 (6.34-860.62)	<0.001

CI: Confidence interval, IPI: Integrated pulmonary index.

($p < 0.001$) and EtCO₂ ($p < 0.001$, $p = 0.003$) were significantly higher compared to those with no episodes of hypoxia or serious hypoxia. Episodes of tachypnoea, tachycardia and bradycardia were not significantly different between hypoxia and serious hypoxia patients ($p > 0.05$) (Table 4).

Patients with IPI=1 had a manifold increased risk (odds ratio [OR]: 10.91; 95% confidence interval [CI]: 2.06 to 57.66) for experiencing an episode of hypoxia when compared to those with IPI>1 ($p = 0.005$). Patients with IPI=1 had a higher risk of episode of serious hypoxia than IP>1 (OR: 73.89; 95% CI: 6.34-860.62) ($p < 0.001$) (Table 5).

Discussion

IPI monitoring is important in clinical practice as it is a non-invasive, dynamic, real-time and continuous measurement method that reflects respiratory status with high specificity and sensitivity, and enables respiratory problems to be identified early on.⁶ The algorithm for calculating the IPI value is based on the Fuzzy Logic Mathematical Model, which mimics the human thought process and calculates the result by assessing the variables against specified probabilities.¹⁴ IPI monitoring can offer a single value for evaluating ventilation and oxygenation, which can be shown on the monitor constantly as numerical data or as a wave form. This

device has been authorised for use by the United States Food and Drug Administration (FDA).¹⁵

The first investigation of IPI was conducted by Taft et al.⁶ who had a team of 18 professionals, including nurses, physiologists, anaesthesiologists and respiratory therapists. Later, Ronen et al.¹⁶ conducted a study that had 22 professionals consisting of nurses, doctors, anaesthetists and respiratory therapists experienced in respiratory monitoring. The study

established an algorithm, and the authors concluded that the derived IPI value precisely and significantly identified all major respiratory episodes with a high level of sensitivity and specificity¹⁶.

In the light of literature^{6,16}, the current study sought to investigate whether IPI detects changes in ventilation status early in patients undergoing GIT endoscopy as well as to evaluate possible risk factors associated with hypoxia and severe hypoxia amongst parameters used in the calculation of IPI.

An earlier study evaluated the use of IPI in reducing respiratory complications related to sedation, and compared standard monitoring and capnographic monitoring in patients undergoing upper GIT endoscopy¹⁷. The authors reported no difference between two groups with regards to the mean decrease in oxygen saturation, which was the study's primary endpoint. However, apnoea episodes were more frequently observed in patients that received standard monitoring. The time from apnoea to hypoxia was 21±5 seconds, and the time from IPI≤6 to apnoea was 22±4 seconds. These numbers are comparable to those found in the current study. However, in the former study, the time for the development of hypoxia was not assessed in relation to other variables.

Peveling-Oberhag et al.¹¹ compared two groups of patients who underwent percutaneous endoscopic gastrostomy. One group received standard monitoring, while the other also underwent capnography. The follow-up was blinded in the study, which reported that hypoxia and severe hypoxia were significantly less in the capnography group. The mean time from apnoea to

hypoxia and severe hypoxia was reported to be 83.4 seconds and 98.6 seconds, respectively. These values are higher than the values in the current study. This is attributable not only to differing patient characteristics, but also to the fact that in the current study, capnographic data was known and interventions were made when necessary, whereas in the other study, the researchers were blinded to capnographic data and were, therefore, unable to intervene.

In addition, unlike other studies, times from apnoea, EtCO₂, IPI=1 and IPI<7 to hypoxia and severe hypoxia were also measured in the current study. To the best of our knowledge, there exists no previous study that has measured these times. Data showed that the time from IPI=1 to hypoxia or severe hypoxia was similar to the time from apnoea or EtCO₂=0 to hypoxia or severe hypoxia. Therefore, IPI=1 was found to be as important as apnoea and EtCO₂=0 in detecting an impending hypoxia or severe hypoxia event.

The secondary outcome measure of the current study was the determination of risk factors for the development of hypoxia and severe hypoxia. When sensitivity and specificity was calculated for the evaluated parameters, IPI=1 had a sensitivity of 88% and specificity of 67%, IPI<7 had a sensitivity of 100% and specificity of 42%, EtCO₂=0 had a sensitivity of 66.7% and specificity of 73.2%. Apnoea had a sensitivity of 83.3% and specificity of 68%, respectively.

Micheal et al.¹⁷ reported the sensitivity of IPI<7 and IPI=1 to be 82% and 81%, respectively, for the prediction of hypoxia, whereas the specificity was reported as 7% and 13%, respectively. Gozal et al.¹⁸ assessed the reliability of capnographic monitoring in detecting respiratory issues, such as hypoxia, hypercapnia and apnoea in children undergoing deep sedation, and reported a specificity of 98%, indicating that the IPI monitor may be useful for monitoring paediatric patients undergoing deep sedation, particularly for healthcare personnel with limited experience. Garah et al.¹⁹ reported the sensitivity and specificity of IPI<4 to be 97% and 89%, respectively, for predicting the development of hypoxia. The higher sensitivity reported in the current study is due to the fact that apnoea, bradypneic and hypopneic ventilation were also a primary outcomes in addition to hypoxia or severe hypoxia.

Apnoea, IPI=1, IPI<7 and EtCO₂=0 all exhibited high sensitivity in the current study and were found to be statistically significant risk factors for the development of hypoxia and severe hypoxia. However, there was no association between other measures (tachypnoea,

tachycardia and bradycardia) and hypoxia and severe hypoxia. The development of hypoxia and severe hypoxia was also found to be strongly correlated to IPI=1. Multivariate analysis demonstrated that patients with IPI=1 were 10.91 times more likely to have hypoxia and 73.89 times more likely to have severe hypoxia compared to those with IPI>1. Therefore, IPI appeared to be better suited to procedures where the risk of respiratory failure was greater.

The current study has limitations owing to its retrospective design. The study population consisted of patients who were monitored with capnography under sedation and who underwent necessary interventions according to capnography data. Therefore, the number of apnoea, EtCO₂=0, IPI=1, IPI<7, hypoxia and serious hypoxia events were less than what would be expected without capnography monitoring. Furthermore, patients were routinely given 2 L/min oxygen through nasal cannula which potentially decreased the number of hypoxic or serious hypoxic episodes.

Conclusion

Time from apnoea, ETCO₂=0 and IPI=1 to a hypoxic or severe hypoxic event carried similar values, and these parameters were significant risk factors for the development of hypoxia. IPI=1 was the most important independent risk factor for the development of hypoxia and severe hypoxia.

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Author's Contributions

HKC: Data collection, analysis of relevant information and drafting.

AA and HKC: Clinical patient management

AA, HKC and ZD designed the article, critical revision of the paper, and submission.

All authors read and approved the final manuscript.