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The Role of the Integrated Pulmonary Index in Determining Respiratory Complications in Patients Undergoing Upper Gastrointestinal Endoscopy Under Sedation

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Abstract

Objective: In this study, we aimed to evaluate the respiratory complications defined by the Integrated Pulmonary Index (IPI) in patients with comorbid risk factors who underwent Upper gastrointestinal endoscopy (UGE) under sedation.

Methods: This cross-sectional, prospective study was conducted with 157 patients, aged over 18 years, in our endoscopy unit between July 2020 and December 2020. Patients' demographic data, body mass index (BMI), ASA class and comorbidities were recorded. The mean arterial pressure (MAP), and HR, RR, SpO2, EtCO2 for the IPI were measured as baseline values and 5 minutes of the procedure and compared between two groups as the patients who developed (Group I) and did not develop (Group II) complications.

Results: The mean BMI value was statistically significantly higher in Group I compared to Group II ($p<0.001$). The mean HR was statistically significantly higher and IPI score significantly lower in Group I than in Group II before the procedure ($p=0.013$, $p=0.01$; respectively). The mean SpO2, EtCO2 and IPI values were statistically significantly lower in Group I compared to Group II at 5 minutes of the procedure ($p=0.001$, $p=0.004$, $p=0.010$; respectively). The frequency of comorbidities was statistically significantly higher in Group I. In the logistic regression analysis, BMI value was found as an independent factor affecting the development of respiratory complications.

Conclusion: The mean IPI scores dropped significantly in patients who developed complications, mainly due to the decreases in EtCO2 and SpO2 values at 5 minutes of the procedure. BMI was determined as a risk factor for the development of respiratory complications. IPI monitoring can provide guidance during sedation of patients with comorbid diseases undergoing UGE.

Key words: Anesthesia, endoscopy, integrated pulmonary index, respiratory complications, monitoring

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Introduction

Upper gastrointestinal endoscopy (UGE), also known as esophagogastroduodenoscopy (EGD), is an prominent procedure performed for screening, diagnosis and treatment of various GI diseases, demand for which is consistently increasing (1, 2). Diagnostic indications for UGE vary in a wide spectrum from persistent upper abdominal pain to chronic symptoms of gastroesophageal reflux disease (GERD), alarming symptoms such as anorexia, and surveillance for malignancy, while therapeutic indications may include removal of a foreign body, upper GI bleeding control and placement of draining or feeding tubes (3). Over 1.2 million diagnostic and therapeutic UGE procedures were performed in the United Kingdom in 2016 (4).

Although UGE can be performed without sedation, today the majority of UGE procedures are performed while the patient is sedated (5). Sedation can significantly increase cooperation and satisfaction of patients and help them to more easily undergo subsequent endoscopies by decreasing vomiting, gag reflex and dizziness (6, 7). However, especially the patients undergoing UGE under sedation should be assessed for comorbid risk factors that increase sensitivity to sedative medications, including chronic pain; advanced chronic lung disease; pulmonary hypertension; coronary artery, liver, or renal diseases; obstructive sleep apnea and anxiety disorders (8).

On the other hand, it is well known that although rare, various respiratory complications can occur in UGEs performed under sedation. Adverse respiratory events seen in UGE procedures range from minor complications such as changes in oxygen saturation to significant major complications, including respiratory arrest (9). It has been that oxygen saturation fell below 90% in 57% of the patients (19) and that short-term mask ventilation may be required in 0.4% of patients and endotracheal intubation in 0.09% of patients, especially during UGE procedures (11). Many guidelines recommend monitoring of basic vital parameters such as oxygen saturation, heart rate and blood pressure sedation applications for UGE (12, 13).

The Integrated Pulmonary Index (IPI™, Medtronic, Dublin, Ireland) combines four parameters such as ventilatory frequency (VF), EtCO2, pulse rate (PR) and SpO2 into one unitless score between 1 and 10 for real-time monitoring of vital parameters (14). This numerical value provides a quick assessment of the patient's clinical condition.

The correlation between IPI respiratory physiological parameters in patients undergoing surgery and colonoscopy has been reported (15, 16). However, there is only limited evidence on its role and usefulness in other clinical situations, including upper GI endoscopy. Therefore, in this study, evaluation of the respiratory complications defined by IPI in patients with comorbid risk factors who underwent UGE under sedation was aimed.

Methods

Study Design and Patients

Our study was designed as a cross-sectional, prospective study and conducted in the endoscopy unit of our hospital between July 2020 and December 2020. Patients aged over 18 years with physical status classified as ASA II-III according to the American Society of Anesthesiologists (ASA) guidelines were included in the study.

Patients aged under 18 years, those with ASA III-IV; patients with hypoxemia (SpO2≤ 90%), bradycardia (heart rate < 50 bpm) or hypotension (systolic blood pressure < 90 mmHg) before the procedure, pregnant patients and those without written consent were excluded from the study.

Data Collection

The UGE procedures were performed under sedation with propofol or fentanyl. Patients' demographic data such as gender and age body mass index (BMI), ASA class, doses of anesthetic agents used, procedure duration, presence of chronic obstructive pulmonary disease, diabetes mellitus (DM), hypertension (HT), ischemic heart disease (IHD), obesity and smoking status were recorded. Respiratory failure and the need for mask ventilation occurring during the procedure were monitored. The patients were evaluated in two groups as those who developed respiratory complications during the procedure (Group I) and the patients who did not develop respiratory complications (Group II).

All patients were monitored with standard electrocardiogram, non-invasive arterial blood pressure and administered 2 L/min oxygen via a nasal cannula with a port from which the exhaled CO2 content could be sampled. In addition, the patient was also monitored with the IPI index that integrates time-based CO2 graphic waveform via CO2 sampling line, end-tidal CO2 pressure (EtCO2; mmHg), respiratory rate (RR; breaths per minute), and pulse rate via an integrated pulse oximeter (SpO2). The IPI index incorporates these four parameters into one score between 1 and 10 as seen in Table 1.

Table 1. The Integrated Pulmonary Index (IPI) scoring system

IPI Scores	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

IPI scores were obtained using a portable bedside monitor (Capnostream 20; Oridion Medical, Needham, MA, USA). Heart rate (HR) and peripheral oxygen saturation (SpO2) values were recorded by using an integrated pulse oximeter (Nellcor, Covidien, Boulder, CO, USA). The mean arterial pressure (MAP), and HR, RR, SpO2, EtCO2 for the IPI were measured as baseline values and 5 minutes of the procedure. The data obtained were compared between the two groups.

The primary outcome of the study was the difference between baseline and 5 minutes SpO2, EtCO2 and IPI values in the patients who experienced respiratory complications during the procedure (Group I) and the patients who did not experience respiratory complications (Group II).

Sedation Procedure

IV cannulation was carried out for sedation in patients who will undergo diagnostic UGE without premedication. The induction dose for sedation was administered with fentanyl 1 mcg/Kg (Talinat® 0.5 mg/10 mL ampul, VEM, Istanbul, Turkey) or propofol 0,5- 1 mg/Kg (Propofol® 1% 10 mL ampul, Fresenius, Uppsala, Sweden), and 10 or 20 mg propofol bolus doses were added with titration, when deemed necessary. The starting dose was 0.5-1 mg/kg and if needed 10-20 mg bolus doses were added. The patients were clinically monitored by an independent anesthesiologist throughout the procedure. Based on standard monitoring parameters and clinical observation, SpO2 < 92% and/or RR ≤ 8,20 % decrease in EtCO2 from baseline value and loss of spontaneous breathing for more than 60 seconds were considered respiratory complications. In the case of respiratory complications, the following actions were carried out: (1) patient stimulation, (2) cessation of the IV drug, (3) chin lift and jaw thrust maneuver, (4) increasing the oxygen supply, and in case of necessity (5) endotracheal intubation.

Statistical analysis

The data obtained in this study were statistically analyzed using SPSS for Windows version 22.0 (SPSS, Statistical Package for Social Sciences, IBM Inc., Chicago, IL, USA). Normality of the variables was analyzed with Kolmogorov-Smirnov test. Continuous variables are explained as mean±standard deviation or median, and categorical variables as frequency and percentage. The independent samples t test was used for the comparison of numerical data between independent groups. Logistic regression analysis was used to eliminate possible interactions of parameters that may affect respiratory complications. $p<0.05$ values were considered statistically notable.

The sample size was calculated as 150 by using the G*Power 3.1.9.7 software with 84% power, the effect size as 0.50 and $\alpha=0.05$.SPSS software (SPSS, Inc., Chicago, IL, USA).

Results

A total of 164 patients undergoing UGE under sedation were included in the study. Four patients with missing data and three patients who left were excluded from the study. Finally, the study was completed with 157 patients. The patients were divided into two groups according to development of respiratory complications as Group I (53 patients with complications) and Group II (104 patients without complications). The mean age was found as 62.64±8.01 years in Group I and 62.82±10.8 years in Group II. The female/male ratio was found as 30/23 in Group I and 46/48 in Group II. No statistically notable disparity was found between the two groups in terms of gender and age (both $p>0.05$). The mean BMI value was statistically notably higher in Group I compared to Group II ($p<0.001$) (Table 2).

The mean MAP and IPI parameters including HR, RR, SpO2 and EtCO2, and IPI scores were measured before the procedure and at 5 minutes of the procedure. The mean HR was statistically significantly higher and IPI score was notably lower in Group I than in Group II before the procedure ($p=0.013$, $p=0.01$; respectively). The mean SpO2, EtCO2 and IPI values were statistically significantly lower in Group I compared to Group II at 5 minutes of the procedure ($p=0.001$, $p=0.004$, $p < 0.001$; respectively). There was no notable disparity between the two groups in terms of the other parameters before

the procedure and at 5 minutes (for all p>0.05) (Table 3).

Table 2. Demographic features and endoscopic data of the patients

	Group I (n=53, 34%)	Group II (n=104, 66%)	p values
Gender F/M, n	30/23	46/48	0.142**
ASA II/III, n	30/23	59/45	0.988**
Age (years)	62.64±8.01	62.82±10.8	0.917*
BMI (Kg/m2)	32.87±6.46	27.77±3.66	**<0.001***
Operation time (min)	10.20±4.92	10.55±4.74	0.155*
Propofol dose (mg)	100.57±32.72	105.48±27.33	0.321*
Fentanyl dose (µgr)	46.70±18.37	46.17±19.07	0.864*

ASA: American Society of Anesthesiologists; BMI: Body Mass Index
*Independent samples t test; **Pearson's Chi-square test

Comorbidity status of the groups was analyzed (Figure 1). Accordingly, the frequency of COPD (43% vs 24%), obesity (47% vs 20%) and having risk factors ≥2 (60% vs 30%) were found to be statistically notably higher in Group I compared to Group (II) (p=0.01, p<0.01, p<0.01; respectively).

The IPI values were statistically notably lower in Group I patients with comorbidities compared to Group II patients with comorbidities at 5 minutes of the procedure (for all p<0.05) (Table 4).

Table 3. IPI scores, IPI parameters and MAP values before the procedure and at 5 minutes

Parameter	Time	Group I	Group II	p
HR (bpm)	baseline	83.47±15.67	76.98±14.23	**0.013**
MAP (mmHg)	baseline	102.87±18.67	101.38±19.61	0.642
SpO_2 (%)	baseline	96.42±2.72	97.10±2.1	0.167
RR (breaths per minute)	baseline	20.51±5.18	19.37±4.55	0.176
$EtCO_2$ (mmHg)	baseline	32.06±6.5	33.03±5.02	0.343
IPI	baseline	8.09±2.03	8.90±1.23	**0.010**
HR (bpm)	5 minutes	78.00±15.031	75.19±12.92	0.225
MAP (mmHg)	5 minutes	92.74±18.472	89.20±20.23	0.288
SpO_2 (%)	5 minutes	91.75±2.80	96.14±2.608	**0.001**
RR (breaths per minute)	5 minutes	17.94±6.386	17.87±4.752	0.938
$EtCO_2$ (mmHg)	5 minutes	28.17±8.982	32.18±5.961	**0.004**
IPI	5 minutes	4.36±0.901	8.65±1.077	**<0.001**

HR: Heart Rate, MAP: Mean Arterial Pressure, SpO2: Peripheral Oxygen Saturation, RR: Respiratory Rate, EtCO2: End-tidal Carbon Dioxide, IPI: Integrated Pulmonary Index (Independent Samples t Test)

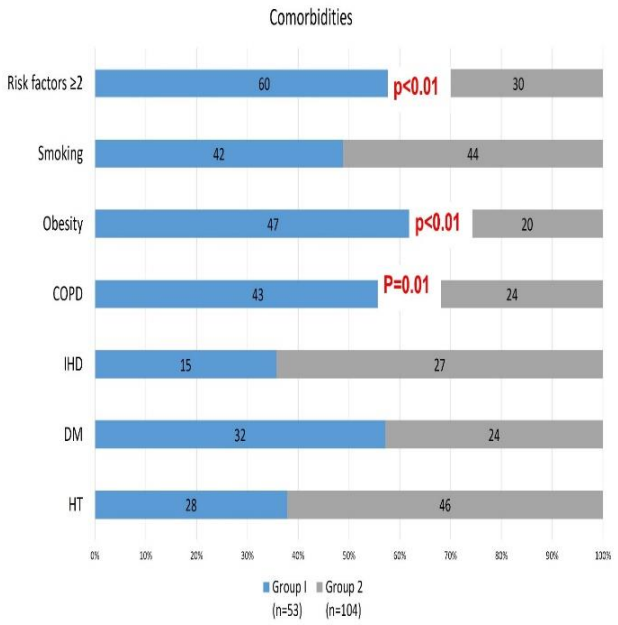

Figure 1. Frequency distribution of comorbidities between the groups

Figure Footnote:COPD: Chronic Obstructive Pulmonary Disease, IHD: Ischemic Heart Disease, DM: Diabetes Mellitus, HT: Hypertension. Chi-square test was used for the comparisons.

Table 4. IPI scores at 5 minutes of the procedure in patients with comorbidities

	IPI VALUES (5 MINUTES)		
	Group I	Group II	p
	mean ± SD	mean ± SD	
HT	4.50±0.63	8.71±1.06	**<0.001**
DM	4.00±0.86	8.68±1.03	**0.001**
IHD	4.50±0.76	8.79±1.07	**<0.001**
Smoking	4.59±0.67	8.46±1.90	**<0.001**
COPD	4.44±0.78	8.67±1.11	**<0.001**
Obesity	4.28±0.90	8.67±1.11	**<0.001**
Risk Factors ≥2	4.38±0.80	8.66±1.10	**<0.001**

COPD: Chronic Obstructive Pulmonary Disease, IHD: Ischemic Heart Disease, DM: Diabetes Mellitus, HT: Hypertension.
Mann-Whitney U test was used for the comparisons.

A logistic regression analysis was performed to determine the factors affecting respiratory complications during UGE under sedation. Age, BMI, smoking, HT, DM, IHD and COPD variables were included in the analysis. As a result, BMI value was found as an independent factor affecting the

development of respiratory complications (OR:1,274; 95% CI: 1,159-1,400; p<0.05).

Discussion

Upper GI endoscopy procedures under sedation have been associated with minor complications such as decreased oxygen saturation and heart rate. Hypoxia during UGE is a well-known complication. The incidence of hypoxia related to endoscopic sedation has been reported between 6–18% depending on the drug and dosage (17). In addition, changes in respiratory rate and end-tidal carbon dioxide may also be seen. However, it is not exactly clear whether these complications are the result of sedation or the endoscopy procedure itself. In our study, we investigated the role and usefulness of the integrated pulmonary index (IPI), which incorporates four vital parameters into a unique score between 1 and 10, in UGE procedures performed in patients with comorbidities who underwent UGE under sedation. Procedure time were similar between the group of patients who developed complications (Group I) and the group of those who did not develop (Group II).

Obesity (BMI ≥30 kg/m2) has been associated with reduced oxygen saturation and hypoventilation (18, 19). In our study, the mean BMI value was higher in the patients who developed complications (32.87 kg/m2 vs 27.77 kg/m2) during UGE, including a decrease in oxygen saturation. In addition, we found with the logistic regression analysis that BMI was an independent factor affecting the development of complications during UGE. In a study by Geng et al., BMI was found to be a useful predictor of hypoxia during GI endoscopy (20). In a retrospective study by Kilic et al. with 1,172 patients investigating the effects of obesity on sedation related complications, the rate of patients who developed desaturation <80% for 3 minutes during endoscopy procedures was found as 7.7% in patients with a BMI values of 25-30 kg/m2 and 14.7% in patients with a BMI value >30 kg/m2 (21). In another study by Wani et al., increasing BMI values were associated with increased frequency of airway maneuvers and hypoxia during advanced endoscopy procedures (22). In this context, our results were consistent with the literature.

The IPI is an algorithm that combines the benefits of ventilation monitoring and oxygenation monitoring and helps the medical team respiratory status of the patient looking at a single parameter. In our study, we used IPI scores to control respiratory events during UGE procedures under sedation and compared the IPI scores between patients who developed complications and those who did not. Based on standard monitoring parameters and clinical observation, patients with a SpO2< 92% and/or RR ≤ 8 and loss of spontaneous breathing for more than 30 seconds were considered to develop respiratory complications. In the patients with complications, the mean IPI score dropped to 4.36 at 5 minutes of the procedure from the baseline value of 8.09. In addition, the mean IPI scores were notably lower in the patients with complications compared to those without complications both at baseline and 5-minute values. In a study by Michael et al., standard monitoring was compared with standard monitoring + IPI scoring in patients undergoing percutaneous endoscopic gastrostomy under sedation. Capnography and IPI readings were recorded for all patients but were only viewable to the endoscopic staff in the standard monitoring group. the mean IPI was found as 8.82±1.62 in the standard group and 9.33±1.11 in the IPI group with no notable difference between them (p=0.06) (23). In another study by Veassen et al. the IPI value of patients undergoing UGE under sedation dropped to 8.89 ± 1.132 in the beginning of the endoscopy from 9.1±1.071 at the beginning of anesthesia induction (24). In a study by Yildirim et al. with ASA I-III patients undergoing cataract surgery under sedation, the mean IPI value was found as 8.84±1.86 at baseline and 8.1±2.48 at 5 minutes of the surgery with no significant difference (p=0.06) (15). However, these studies included no groups with and without complications. When all patients were evaluated in our study, the mean IPI value was found as 8.63±1.59 at baseline and 7.36±2.20 at 5th minute with statistically significant difference (p<0.000). We think that this difference is related to the high ASA groups of the patients included in our study.

There is no consensus on the effectiveness and usefulness of the IPI scoring in patients undergoing endoscopic procedures under sedation. In a study by Vaessen et al. evaluating IPI scores for the detection of respiratory events in patients undergoing UGE under sedation, it was reported that the use of IPI cannot be recommended in UGE, especially when CO2 was used (24). In another study by Berkenstadt et al., a limited agreement was found between respiratory physiological parameters and IPI scores (16).

In our study, the mean IPI scores were statistically significantly lower at 5 minutes of the procedure in patients with comorbidities who developed complications compared to those with comorbidities but who did not develop complications, suggesting that the presence of comorbidities did not affect IPI scores. In fact, the only factor affecting the

development of complications was found as BMI in the logistic regression analysis, supporting this opinion.

Recently, EtCO2 has been increasingly used in routine monitoring in operating rooms and intensive care units. It has been reported that EtCO2 monitoring is crucial especially during upper GI endoscopies (25). In our study, the mean 5th minute EtCO2 and SpO2 values were notably lower in the patients who developed complications (p=0.001, p=0.004; respectively), which may explain the lower IPI values at 5 minutes in these patients. In the present study also IPI values were affected by EtCO2 and SpO2, while the other two components, HR and RR did not significantly change at 5 minutes, raising questions about the utilization of the IPI. Hence, we believe that further more comprehensive prospective studies with a larger series of patients are needed to draw more definite conclusions.

Study Limitations

The main limitation of the ourstudy is the relatively small number of patients. In addition, standard monitoring could be statistically compared with the IPI scoring. Finally, the measurements were limited with baseline and 5th minutes. However, its prospective nature makes our study strong, and our results could be guiding for future prospective studies about UGE procedures that are limited in the literature.

Conclusion

IPI combines oxygenation and ventilation parameters, allowing a quick and easy assessment of patients' respiratory status. In this study, in which the ASA III-IV patient group was included, the mean IPI scores decreased significantly in patients who developed complications, especially due to the decreases in EtCo2 and SpO2 values at the 5th minute of the procedure. BMI was determined as a risk factor for the development of respiratory complications. IPI monitoring can offer guidance during sedation of patients with comorbid diseases undergoing UGE. Our results can contribute to the studies on this subject in the literature.

Ethics Committee Approval: This study was conducted with the approval of the ethics committee of Recep Tayyip Erdogan University Faculty of Medicine, Non-Invasive Clinical Research Ethics Committee. (Ethics Committee Approval Date:01.07.2020 Decision no: 2020/138)
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