

# Clinical analysis of propofol deep sedation for 1,104 patients undergoing gastrointestinal endoscopic procedures: A three year prospective study

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## Abstract

**AIM:** To analyze the hemodynamic and respiratory effects of propofol on patients undergoing gastroscopy and colonoscopy.

**METHODS:** In this prospective study, conducted over a period of three years, 1,104 patients referred for a same day GI endoscopy procedure were analyzed. All patients were given a propofol bolus (0.5-1.5 mg/kg). Arterial blood pressure (BP) was monitored at 3 min intervals and heart rate and oxygen saturation (SpO<sub>2</sub>) were recorded continuously by pulse oximetry. Analyzed data acquisition was carried out before, during, and after the procedure.

**RESULTS:** A statistically significant reduction in mean arterial pressure was demonstrated ( $P < 0.001$ ) when compared to pre-intervention values, but severe hypotension, defined as a systolic blood pressure below 60 mmHg, was noted in only 5 patients (0.5%). Oxygen saturation decreased from 96.5% to 94.4% ( $P < 0.001$ ). A critical decrease in oxygen saturation ( $< 90\%$ ) was documented in 27 patients (2.4%).

**CONCLUSION:** Our results showed that propofol provided good sedation with excellent pain control, a short recovery time and no significant hemodynamic side effects if carefully titrated. All the patients (and especially ASA III group) require monitoring and care of an anes-

## INTRODUCTION

Gastrointestinal endoscopy remains to date an essential diagnostic and therapeutic tool. Patient comfort during the procedure is of paramount importance for successful completion of the examination<sup>[1,2]</sup>. A significant subset of patients is unable to tolerate gastrointestinal endoscopic procedures without sedation<sup>[3,4]</sup>. Midazolam and benzodiazepines are most commonly used, often in combination with pethidine, whereas anesthetic agents are less frequently used because oversedation may induce respiratory depression, hypotension, and other cardiopulmonary complications.<sup>[5-8]</sup> Optimal administration of conscious sedation and patient monitoring during endoscopy has not been adequately emphasized so far<sup>[9]</sup>.

The optimal strategy of conscious sedation should be tailored to the individual patient, based on the experience of the gastroenterologist and anesthesiologist. Oversedation may induce respiratory depression and delayed recovery in elderly patients and in those with inherent cardiopulmonary compromise. Hypoxemia and hypotension represent the majority of complications observed, especially in upper intestinal endoscopy<sup>[11]</sup>, and may occur more frequently during endoscopic procedures than during anesthesia.

Gastrointestinal procedures require careful patient monitoring especially in the high-risk patient population. Patient vital signs have been monitored in less than 25.9% of cases, in the published literature<sup>[9]</sup>.

Table 1 ASA physical status classification

ASA group	Procedure			Total
	Colonoscopy	Gastroscopy	Both procedures	
I	335	209	165	709
II	172	90	98	360
III	14	11	10	35
Total	521	310	273	1104

ASA-American Society of Anesthesiology.

The purpose of this study was to analyze the hemodynamic and respiratory effects of propofol on patients undergoing gastroscopy and colonoscopy and thus determine whether the monitoring and care of an anesthesiologist is required.

## MATERIALS AND METHODS

### Patients

We analyzed 1104 patients (639 women and 465 men) admitted for a same day colonoscopy (521 patients), gastroscopy (310 patients) or both procedures (273 patients). The study was conducted prospectively over a three year period, from the 1<sup>st</sup> January 2001 to the 1<sup>st</sup> January 2004, at the Bates Clinic in Zagreb, Croatia. The median age of our patients was 53 years (range 17-88). Age, sex, body weight, blood pressure, heart rate, electrocardiogram, oxygen saturation, as well as patient history including current medication were recorded. We used the American Society of Anesthesiology classification system (ASA grades I-IV) to stratify patients by risk prior to the gastrointestinal procedure. Seven hundred and nine patients were in ASA group I (healthy patients), 361 in ASA II (patients with disease of one body system), and 35 in ASA III (patients with disease of more than one body system) (Table 1). After written informed consent had been obtained, an intravenous cannula was inserted. All patients were monitored throughout the procedure by the anesthesiologist.

### Procedure

The patients were given an intravenous propofol (2,6-diisopropylphenol, Diprivan, Astra Zeneca, USA) bolus (0.5-1.5 mg/kg). The required dose was calculated by the anesthesiologist based on the patient's weight, age, physical condition, and estimated duration of procedure. A mean dose of 135 mg (60-480 mg/kg) of propofol was administered. After an initial dose of 0.5-1.5 mg/kg (ASA I and II) or 0.25-0.5 mg/kg in patients ASA class III or over 70 years, the additional bolus injection was administered to maintain the sedation if needed. Supplemental nasal oxygen was administered at 4 l/min during the procedure. Oxygen saturation and heart rate were monitored continuously by pulse oximetry and blood pressure was recorded at three minute intervals. These values were obtained before, during and after the endoscopic procedure (Table 2). Following the completion of the procedure, the patients were transferred to a recovery room and were closely observed for 30 min. The anesthesiologist recorded an overall pain score (using graded questionnaire describing pain

Table 2 Data on basic laboratory parameters measured before, during and after GI procedures

Parameter	Findings in patients (mean <sup>±</sup> /SD)			Number of monitored patients		
	Before procedure	During procedure	After procedure	Before procedure	During procedure	After procedure
SBP (mmHg)	140.8 <sup>±</sup> / -26.0	112.2 <sup>±</sup> / -25.3	114.6 <sup>±</sup> / -23.7	1 096	880	1 037
DBP (mmHg)	80.6 <sup>±</sup> / -13.3	68.4 <sup>±</sup> / -14.1	70.1 <sup>±</sup> / -12.9	1 096	880	1 035
HR (beats/min)	88.4 <sup>±</sup> / -19.1	81.3 <sup>±</sup> / -14.3	80.1 <sup>±</sup> / -13.9	1 012	888	1 049
SpO <sub>2</sub> (%)	96.5 <sup>±</sup> / -2.9	94.4 <sup>±</sup> / -4.1	95.3 <sup>±</sup> / -3.4	997	885	1 046

Abbreviations: SBP-systolic blood pressure, DBP-diastolic blood pressure, HR-heart rate, SpO<sub>2</sub>-oxygen saturation, SD-standard deviation.

as: no pain, mild, moderate and severe pain), complications and recovery time.

### Statistical analysis

Contingency tables were made for qualitative data and distribution parameters (mean, standard deviation, minimum and maximum) were calculated for all measured variables (systolic and diastolic blood pressure, heart rate, oxygen saturation and propofol per kg body weight). Paired t-test was used to test differences between pairs of values for all measured hemodynamic variables before, during and after the procedure.

## RESULTS

We analyzed arterial blood pressure, oxygen saturation and heart rate (Table 2). Blood pressure and heart rate decreased during the procedure ( $P < 0.0001$ ) and increased after ( $P < 0.0001$ ) an initial value. Our results showed that propofol in dosages of 0.5-1.5 mg/kg decreased the systolic blood pressure from 149.8 to 112.2 mmHg, diastolic blood pressure from 80.6 to 68.4 mmHg and heart rate from 88.4 to 81.3 beats/min. Hypotension, defined as a blood pressure below 60 mmHg, was recorded in 5 patients and they received a 500 mL normal saline bolus. Bradycardia, defined as a heart rate less than 50/min, was recorded in 7 patients (0.6%) and they received 0.5 mg of atropine. All medications were administered by the attending anesthesiologist. Oxygen saturation also decreased during the procedure from 96.5% to 94.4% ( $P < 0.001$ ). Oxygen saturation of less than 90% was documented in 27 patients (2.4%). Seven of them were in ASA class III with cardiopulmonary disease, 14 patients with hypertension and obesity and 6 patients were older than 80 years. All hypoxemic episodes occurred in patients undergoing an upper GI examination. No episodes of apnea occurred and mechanical ventilation was not employed in any of our patients. The hypoxemia proved to be transient in all the patients. In our study 3 patients developed ventricular premature beats whereas 5 patients went into a supraventricular tachycardia with a ventricular rate exceeding 140 beats/min. The endoscopic procedures themselves caused no complications. Total

colonoscopy was achieved in all but 6 patients who had subtotal stenosis. None of our patients reported any pain. Median recovery time was 7 min (range 5-15). Five patients had nausea but no intervention was needed. There were no serious respiratory or hemodynamic complications.

## DISCUSSION

Our choice of agent for the establishment of conscious sedation was propofol, a short acting anesthetic agent. In comparison with conventional sedation using midazolam or benzodiazepines, it provides a considerably more rapid onset of action and shorter recovery time<sup>[10,19,20]</sup>. We believe it is a safe alternative for patients undergoing endoscopic procedures. In this study, none of the patients sedated with propofol reported any pain, and the mean recovery time was 7 min (5-15 min).

The choice of sedative in GI procedures is largely operator dependent, but generally consists of benzodiazepines used either alone or in combination with an opiate<sup>[5-8]</sup>. Such combination may increase the risk of oxygen desaturation and cardiorespiratory complications<sup>[2,4,9]</sup>. Trojan *et al*<sup>[14]</sup> demonstrated that the residual effects of midazolam on psychomotor function could be documented for at least 1 h after its administration. Paradoxical reactions, including hyperactive or aggressive behavior have been reported<sup>[4]</sup>. The anesthetic agents, such as droperidol, propofol and general anesthesia are reserved for patients who remain uncooperative on standard regimens or who are perceived to be at high risk for agitation unless a deeper level of sedation is achieved<sup>[15-17]</sup>. General anesthesia is used most commonly in children. Sedation with midazolam, benzodiazepines, analgetics and propofol was administered in many studies by the nurse and the endoscopist<sup>[10,14,18-20]</sup>. In certain settings, assistance from an anesthesiologist may be required. Some authors suggest that GI procedures without sedation are satisfactory<sup>[4,6,9,18]</sup>, but in our previous study<sup>[21]</sup> we showed that 50% of patients without sedation reported the procedure as painful.

Our results showed that propofol in dosages of 0.5-1.5 mg/kg decreased the systolic and diastolic blood pressure and heart rate during the procedure and increased after an initial value. Hypotension and respiratory depression represent the majority of the complications observed<sup>[10,11,22-24]</sup>. In our study only 5 patients had hypotension and 7 patients developed bradycardia. Most of these patients were obese with cardiopulmonary disease and a compromised general physical condition (ASA class III). Electrocardiographic changes during GI procedures, especially gastroscopy, are common and reported in patients with known heart disease as well as otherwise healthy patients<sup>[24]</sup>. Approximately a half of all the complications observed during gastroscopy are of cardiopulmonary origin<sup>[12]</sup>. These rhythm abnormalities in 7 patients were of short duration and caused no hemodynamic compromise.

Monitoring of cardiopulmonary function during endoscopic procedures is of outmost importance and we believe that a significant reduction in morbidity and mortality can thus be achieved. The most widely used

definition of hypoxemia is an oxygen saturation of below 90% and monitoring of oxygen saturation is more sensitive than a clinical detection of cyanosis. Respiratory complications with oxygen desaturation were recorded in 2.4% patients in our study. We prevented hypoxemia with administration of supplementary of 4l/min oxygen. Numerous studies have documented the occurrence of hypoxemia during endoscopy<sup>[6,23-25]</sup>. They reported cardiopulmonary complications with oxygen desaturations in 40-60% of patients with sedation, and some studies have reported desaturation in 40% of unsedated patients<sup>[23]</sup>. Obesity, pulmonary disease, age and mechanical airway obstruction worsened hypoxemia. Their recommendation consisted of pulse oximetry monitoring. Intermittent oxygen desaturation is also common during sleep in normal subject<sup>[25]</sup>. Others showed that hypoxemia can be prevented by providing supplemental oxygen<sup>[5,23]</sup>. Gastrointestinal societies in the United States and United Kingdom issued guidelines for monitoring and oxygen administration<sup>[23,24]</sup>. All patients, and especially those in ASA III group, require monitoring and care of an anesthesiologist. Our results showed that propofol provided good sedation and short recovery time. The procedure is rendered painless and no significant respiratory or hemodynamic deteriorations have been observed. Monitoring of blood pressure, heart rate, ECG and oxygen saturation is necessary, as is supplemental administration of oxygen. While some authors recommended that sedation with propofol by nonanesthetists or nurses<sup>[10]</sup> are acceptable, we believe that conscious sedation administration and monitoring by an anesthesiologist with an inherent high index of suspicion for potential complications might be a safer strategy.

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