#### **Reliability Of Non-Invasive Carbon Dioxide Monitoring During Conscious Sedation For Adult Endoscopic Retrograde Cholangiopancreatography Patients; A Prospective Quasi Study**

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### **Abstract**

**Background:** Many patients develop hypoxia significantly during endoscopic retrograde cholangiopancreatography (ERCP). Monitoring the respiratory  $CO<sub>2</sub>$  non-invasively is easy and relatively inexpensive. End-tidal carbon dioxide ( $E(CO<sub>2</sub>)$  reflects how well  $CO<sub>2</sub>$ ) in the blood is carried to the lungs and exhaled. This study aimed to determine whether non-invasive  $CO<sub>2</sub>$  monitoring (Dual-Guard Device-DGD) could substitute the invasive method.

**Methods:** This quasi-prospective study was conducted on 150 patients scheduled for elective ERCP procedures under conscious sedation. All patients were evaluated for systolic (SBP), diastolic (DBP), mean blood pressure (MBP), heart rate (HR), respiratory rate (RR),  $EtCO<sub>2</sub>$  and peripheral oxygen saturation (SpO<sub>2</sub>) in addition to arterial blood gases (ABG), Ramsay Sedation Scale, participants' satisfaction, and any possible complications.

**Results:** The mean duration of procedures and sedation were  $28.63 \pm 9.5$  and  $41.25 \pm 1.5$ 11.5 minutes, respectively. The mean HR and RR showed a significant ( $p<0.001$ ) increase during follow-up. The mean SBP, DBP, and MBP showed a significant  $(p<0.001)$ decrease, while the mean  $EtCO<sub>2</sub>$  and mean  $SpO<sub>2</sub>%$  significantly increased. The mean pH,  $PQ<sub>2</sub>$  and Sa $Q<sub>2</sub>$  significantly decreased postoperatively ( $p<0.001$ ). In opposition, the mean  $HCO<sub>3</sub>$  level preoperatively was significantly ( $p<0.001$ ) lower than the postoperative level. Most patients recovered within 10 and 15 min. with 600/800 mg of propofol, and 47% of cases reported satisfaction.  $CO<sub>2</sub>$  was significantly higher with ABG than DGD (p<0.001). **Conclusions:** This study revealed poor reliability of non-invasive  $CO<sub>2</sub>$  monitoring (using a Dual-Guard Device) compared to the invasive method (ABG) during conscious sedation for adult ERCP patients.

**Keywords:** Capnography; EtCO<sub>2</sub>; Arterial Blood Gas; Dual-Guard Device; ERCP.

# **Introduction**

Many patients develop hypoxia significantly during the endoscopic retrograde cholangiopancreatography (ERCP) procedure. After sedation induction during endoscopy, oxygen saturation drops in almost all patients and very profoundly in several patients to critically low levels [1].

According to the American Society of Anesthesiologists (ASA), during sedation (deep or moderate), the sufficiency of ventilation should be assessed by continuous monitoring of specific clinical signs and observing for the existence of exhaled carbon dioxide  $(CO_2)$ <sup>[2]</sup>.

Carbon Dioxide is the essential breathing driver and the primary purpose for mechanically ventilating a patient. Monitoring the respiratory  $CO<sub>2</sub>$  noninvasively is easy and relatively inexpensive and has been widely studied  $[3]$ . End-tidal carbon dioxide ( $EtCO<sub>2</sub>$ ) is the  $CO<sub>2</sub>$  level released at the end of exhalation. It reflects the efficiency of carrying carbon dioxide in the blood to the lungs and exhaling it. Available proof demonstrated that measuring  $EtCO<sub>2</sub>$  can indicate pulmonary blood flow and cardiac output [4].

Capnometry presents numeral values for EtCO<sub>2</sub>. On the contrary, capnography provides a further comprehensive measure presented in digital and graphic (waveform) forms [5]. Capnography gives immediate information for ventilation, perfusion, and metabolism <sup>[6]</sup>. It became a part of anaesthesia practice in Europe in the 1970s

and the United States in the 1980s. Now, it is part of the routine monitoring of all patients undergoing general anaesthesia and in acute or pre-hospital facilities [7].

The Dual-Guard lays a principle in endoscopic procedures; it includes an endoscopic bite block with  $CO<sub>2</sub>$  monitoring and oxygen delivery for upper endoscopic procedures. The Dual-Guard improves patient safety and aligns with the guidelines for consciously sedated patients. The Comfort Rest Bite Block fits safely in the mouth, securing both the endoscope and the patient's teeth. Concurrent nasal and oral  $O_2$ delivery and  $CO<sub>2</sub>$  sampling are available for patients undergoing upper GI endoscopy in either a lateral or supine position [8].

An arterial blood gas (ABG) test result can provide more information about the physiological condition of surgical patients. In addition to measuring pH, arterial blood gases can provide data on the sufficiency of oxygenation and ventilation of the patients and specify the underlying source of homeostasis disorders (i.e., respiratory or metabolic)<sup>[9]</sup>.

Hypothesis: This study was designed to define if the non-invasive  $CO<sub>2</sub>$  monitoring (using a Dual-Guard Device) could substitute the invasive method (ABG) and present an early warning sign of hypoventilation during conscious sedation in adult patients undergoing ERCP.

# **Patients And Methods**

This Quasi prospective study was conducted after being approved by the Medical Ethics Committee, Faculty of Medicine, Assiut University, Assiut, Egypt (protocol ID: 1RB17101161 on 27/08/2020) and registration in the ClinicalTrials.gov (ID: NCT04481308 on 21/07/2020). Written informed consents were obtained from all patients before enrolment.

The study included 150 patients (20-50 years old) of both sexes with ASA physical status II and scheduled for elective ERCP procedures under conscious sedation at Assiut University Hospitals from January 2021 to January 2022. Exclusion criteria were the patient's refusal, presence of abnormal renal or hepatic function, history of chronic chest diseases like asthma or COPD, history of systemic illness such as diabetes or hypertension, and cardiac patients.

The targeted patients were allocated to one group without random assignment. All patients were evaluated for hemodynamic variables: systolic blood pressure (SBP), diastolic blood pressure (DBP), mean blood pressure (MBP), heart rate (HR), respiratory rate (RR), end-tidal  $CO<sub>2</sub>$  (EtCO<sub>2</sub>), and peripheral oxygen saturation  $(SpO<sub>2</sub>)$ . In addition to ABG, Ramsay Sedation Scale, participants' satisfaction, and any possible complications were recorded throughout the procedure.

Intraoperative management: Patients were anaesthetized by the same team of anesthesiologists and operated upon by the same surgical team, who was unaware of the study medications. Patients started to receive sedation via propofol (2 mg/kg) and fentanyl (1  $\mu$ g/kg) with 4 liters O<sub>2</sub> flow nasally, and EtCO<sub>2</sub> was monitored non-invasively through the Dual-Guard™ device (Flexicare Medical Ltd), which incorporates an endoscopy bite block with oxygen delivery. CO<sup>2</sup> monitoring was recorded from both the mouth and the nose simultaneously. After induction of sedation and following a modified Alien's test, a radial artery catheter was inserted under local anaesthesia with a complete aseptic technique for measuring arterial blood gas tension and evaluating acid-base status. ABG readings were recorded after induction of sedation (baseline) and at the end of the ERCP procedure.

Data collection: The hemodynamic parameters and  $EtCO<sub>2</sub>$  were recorded at baseline before ERCP, then at 10, 20, and 30 minutes intraoperatively, and the end of the procedure. Ramsay Sedation Scale (RSS) [10] for monitoring the sedation levels of all participants through 6 points  $(1 =$  anxious, restless, or both, 2= cooperative, oriented, and tranquil,  $3=$  responding to commands,  $4=$ brisk response to stimulus, 5= sluggish response to stimulus, 6= no response to stimulus). Participants' satisfaction was reported after the end of the procedure

through a 5-5-point Likert scale  $^{[11]}$  (1 = very satisfied and willing to undergo the same intervention in the future when indicated,  $2 =$ satisfied,  $3$  = neither satisfied nor dissatisfied,  $4 =$  dissatisfied, and  $5 =$  very dissatisfied). Any complications throughout the whole procedure, like postoperative nausea, vomiting, headache, dizziness, somnolence, vertigo, or confusion were recorded and managed accordingly.

The primary outcome was the  $EtCO<sub>2</sub>$ measurements, while the secondary outcomes were haemodynamic measurements, ABG values, time to recovery, total propofol dose, sedation score, complications, and Participants' satisfaction.

Sample size: Sample size calculation was done using  $G^*$ Power 3 software  $[12]$ . A convenient sample composed of 150 patients from all patients scheduled for elective ERCP, fulfilling our inclusion criteria through one year (from the start of data collection), was included in the study. This was according to our hospital records for the last 3 months before the study.

Statistical analysis: Data were verified, coded, and analysed using IBM-SPSS 24.0 (IBM-SPSS Inc., Chicago, IL, USA). The normality of any continuous variables was tested using the Kolmogorov-Smirnov test/Shapiro-Wilk test as appropriate. For continuous variables with more than two interval measurements, the one-way repeated measure ANOVA (RM-ANOVA) test was calculated to test the mean differences of the data that followed a normal distribution and had repeated measures, a post-hoc test was calculated using Bonferroni corrections for pairwise comparisons between the study intervals. For continuous variables with two interval measurements, a paired sample t-test was calculated to test the mean differences of the data that followed a normal distribution and had repeated measures. The interclass correlation coefficient was used to test the reliability of the Dual-Guard device (DGD) in  $CO<sub>2</sub>$  measurement. A significant p-value was considered when it was <0.05.

# **Results**

This study was a quasi-experimental prepost single group design. A total number of 150 patients were recruited for one year and completed the study. The mean age was 49.1  $\pm$  6.6 years, the mean weight was 83.18  $\pm$ 8.3 Kg, and 69 (46%) participants were males, while 81 (54%) participants were females. The mean procedural duration was  $28.63 \pm$ 9.5 minutes, and the mean duration of sedation was  $41.25 \pm 11.5$  minutes (Table 1).

The mean HR showed a significant (p<0.001) steady increase upon follow-up. In contrast, the mean SBP, DBP, and MBP showed a significant  $(p<0.001)$  constant decrease upon follow-up. The mean RR showed a significant  $(p<0.001)$  steady increase upon follow-up. However, all these parameters were still within normal ranges without clinical significance (Table 2).

The mean  $EtCO<sub>2</sub>$  showed a significant (p<0.001) steady increase throughout the intervention. The mean  $EtCO<sub>2</sub>$  preoperatively was significantly lower compared with reading at 10-min, at 20-min, at 30-min, and at the end of the procedure  $(p<0.001)$ . The mean  $SpO<sub>2</sub>$  showed a significant (p=0.003) increase upon follow-up. The mean  $SpO<sub>2</sub>$ preoperatively differed from reading after induction at 10-min, 20-min, and 30-min. Contrarily, it was significantly lower than the reading at the end of the procedure (98.59  $\pm$ 0.7 %) with a p-value of 0.012 (Table 3).

Preoperatively, the mean pH and PO2 levels were significantly (p<0.001) higher than the postoperative levels. In opposition, the mean PCO<sub>2</sub>, HCO<sub>3</sub>, and SaO<sub>2</sub> levels preoperatively were significantly  $(p<0.001)$ lower than the postoperative levels (Table 4).

Recovery time  $\leq 5$  minutes was recorded in only three cases. It was reported that about three-quarters (n=108) of cases between 5 and 10-min and about one-quarter of patients (n=39) had recovery between 10 and 15 min. For the total propofol dose, 42% of participants received a dose of 400 mg, about one-third had a dose of 500 mg, and 37% received a dose of 600/800 mg. According to the Ramsay Sedation Scale, 15.3% of cases were anxious or restless or both, 70% were cooperative and oriented, while 14.7% responded to commands. Regarding patient

satisfaction, the majority of cases were very satisfied (41.3%) or satisfied (47.3%), while the minority were neutral (9.3%), and only three cases (2%) were unsatisfied (Table 5).

Table 6 shows that  $CO<sub>2</sub>$  was significantly higher with arterial blood gas (ABG) compared with Dual-Guard device (DGD). Again, the reliability of DGD was tested using an Interclass Correlation Coefficient (ICC), which revealed poor reliability after induction and at the end  $(p=0.842$  and  $0.551)$ .

#### **Legends of Tables:**

Table 1: Baseline demographics and clinical characteristics of the studied cohort.

Table 2: Effect of procedural sedation on patients' hemodynamic and respiratory rate values.

Table 3: Effect of procedure on  $E(CO_2)$  and peripheral oxygen saturation (SpO<sub>2</sub>).

Table 4: Effect of procedure on the mean ABG values.

Table 5: Follow-up data of the studied cohort.

Table 6: Validity of the non-invasive  $CO<sub>2</sub>$  monitoring DGD against the ABG



**Table 1**: Baseline demographics and clinical characteristics of the studied cohort

Data were presented as Mean  $\pm$  SD or frequency, percentage, and median (range). P-value  $< 0.05$ : Significant.

**Table 2:** Effect of procedural sedation on patients' hemodynamic and respiratory rate values



	Mean $\pm SD$		P value**	
$SBP$ (mmHg)				
Preoperative	$126.07 \pm 14.6$	$1 \text{ vs. } 2 < 0.001$	$2$ vs. $4 = 0.001$	$4 \text{ vs. } 5 = 0.461$
After Induction	$117.87 \pm 17.1$	$1 \text{ vs. } 3 < 0.001$	$2 \text{ vs. } 5 = 0.014$	4 vs. $6 < 0.001$
$10$ -min.	$115.59 \pm 13.7$	1 vs. $4 < 0.001$	2 vs. $6 = 0.637$	$5$ vs. $6 < 0.001$
20-min.	$114.27 \pm 13.4$	$1$ vs. $5 < 0.001$	$3 \text{ vs. } 4 = 0.140$	
30-min.	$114.81 \pm 12.3$	1 vs. $6 < 0.001$	$3 \text{ vs. } 5 = 0.432$	
At End	$118.37 \pm 11.5$	2 vs. $3 = 0.041$	$3 \text{ vs. } 6 = 0.010$	
P-value*	< 0.001			
$DBP$ (mmHg)				
Preoperative	$75.85 \pm 9.3$	1 vs. $2 = 0.379$	2 vs. $4 < 0.001$	4 vs. $5 = 0.925$
After Induction	$75.07 \pm 9.8$	$1 \text{ vs. } 3 = 0.002$	$2$ vs. $5 < 0.001$	4 vs. $6 = 0.082$
10-min.	$73.13 \pm 9.6$	$1$ vs. $4 < 0.001$	$2 \text{ vs. } 6 = 0.014$	5 vs. $6 = 0.084$
20-min.	$72.33 \pm 9.4$	$1 \text{ vs. } 5 < 0.001$	$3 \text{ vs. } 4 = 0.230$	
30-min.	$72.38 \pm 9.2$	1 vs. $6 = 0.003$	$3 \text{ vs. } 5 = 0.237$	
At End	$73.24 \pm 8.5$	$2 \text{ vs. } 3 = 0.003$	$3 \text{ vs. } 6 = 0.868$	
P-value*	< 0.001			
$MBP$ (mmHg)				
Preoperative	$93.71 \pm 11.4$	$1 \text{ vs. } 2 = 0.003$	2 vs. $4 < 0.001$	4 vs. $5 = 0.557$
After Induction	$90.46 \pm 13.3$	1 vs. $3 < 0.002$	2 vs. $5 = 0.004$	4 vs. $6 = 0.028$
$10$ -min.	$88.44 \pm 11.3$	$1 \text{ vs. } 4 < 0.001$	2 vs. $6 = 0.173$	5 vs. $6 = 0.043$
20-min.	$87.47 \pm 12.3$	1 vs. $5 < 0.001$	$3$ vs. $4 = 0.160$	
30-min.	$87.81 \pm 10.9$	1 vs. $6 < 0.001$	$3 \text{ vs. } 5 = 0.403$	
At End	$89.15 \pm 11.1$	$2 \text{ vs. } 3 = 0.011$	$3 \text{ vs. } 6 = 0.388$	
P-value*	< 0.001			
RR (Cycle/min.)				
Preoperative	$17.53 \pm 2.3$	$1 \text{ vs. } 2 < 0.001$	2 vs. $4 = 0.003$	4 vs. $5 = 0.001$
After Induction	$24.26 \pm 3.3$	1 vs. $3 < 0.001$	$2 \text{ vs. } 5 = 0.920$	4 vs. $6 < 0.001$
$10$ -min.	$25.09 \pm 3.6$	$1 \text{ vs. } 4 < 0.001$	$2 \text{ vs. } 6 < 0.001$	$5$ vs. $6 < 0.001$
20-min.	$25.19 \pm 3.1$	1 vs. $5 < 0.001$	$3 \text{ vs. } 4 = 0.749$	
30-min.	$24.23 \pm 3.5$	1 vs. $6 < 0.001$	$3 \text{ vs. } 5 = 0.005$	
At End	$22.59 \pm 2.8$	$2 \text{ vs. } 3 = 0.005$	$3$ vs. $6 < 0.001$	
P-value*	< 0.001			

**Table 2:** Effect of procedural sedation on patients' hemodynamic and respiratory rate values *(Cont.)*

Data were presented as mean  $\pm$  SD. \*Repeated Measure ANOVA test was used to compare the mean difference between groups over time. \*\*Pairwise comparison on a single time interval (Mann-Whitney U-test). P-value < 0.05: Significant.





Data were presented as Mean  $\pm$  SD.

\*Repeated Measure ANOVA test was used to compare the mean difference between groups over time. \*\*Pairwise comparison on a single time interval (Mann-Whitney U-test). P-value < 0.05: Significant.

**Table 4:** Effect of procedure on the mean ABG values



Data were presented as Mean  $\pm$  SD.

P-value <0.05: Significant.





Data were presented as the number of patients (percentage). P-value  $< 0.05$ : Significant.

**Table 6:** Validity of the non-invasive CO<sub>2</sub> monitoring DGD against the ABG



Data were presented as Mean  $\pm$  SD. P-value  $< 0.05$  was considered significant.

\*Paired Sample t-test was used to compare the mean differences between groups.

DGD: Dual-Guard Device, ABG: Arterial Blood Gas

#### **Discussion**

Sedation is a significant ingredient of any gastrointestinal (GI) endoscopic proceedings to help relieve a patient's apprehension and annoyance while improving endoscopic outcomes [13]. Several challenges remain while using sedating agents in GI endoscopy procedures, including cardiopulmonary adverse effects, such as respiratory depression, hypoxemia, or arrhythmias [14]. ABG sampling is not easy every time, and the technique has some considerable limitations, including prior surgeries such as cut-down and insufficient blood circulation in the extremities [15].

Capnography is the process of physiologic monitoring through calculating EtCO2, an efficient measure of respiratory function in patients subjected to sedation [16]. It constantly measures the exhaled respiratory gases, and by understanding the

characteristics of  $CO<sub>2</sub>$  absorptive criteria in the electromagnetic spectrum, it permits the continual estimation of the level of  $CO<sub>2</sub>$ . Through capnographic monitoring, recognizing alveolar hypoventilation before the development of hypoxemia allows a quick alarming sign and time for appropriate management [16-17].

In the current study, the mean HR showed a significant steady increase upon follow-up and was significantly lower when compared to the different readings after induction  $(p<0.001)$ .

In our study, the mean SBP, DBP, and MBP showed a significant  $(p<0.001)$ constant decrease upon follow-up. We were in line with Friedrich et al. <sup>[20]</sup>, who reported that baseline SBP ranged from 69-219 mmHg with a mean of  $136 \pm 23$  mmHg in patients presenting for colonoscopy.

In the current study, the mean  $EtCO<sub>2</sub>$ showed a significant  $(p<0.001)$  steady increase upon follow-up (the mean  $ECO<sub>2</sub>$ after induction was significantly lower than the follow-up readings). Similarly, Miyoshi et al.  $[21]$  reported an insignificant difference in the PaCO<sub>2</sub> mean reading before and after endoscopy (38.7 versus 38.9 mmHg). The mean transcutaneous ( $PtcCO<sub>2</sub>$ ) record was somewhat higher post-intervention than before (39.5 versus 38.7 mmHg), and both values correlate positively.

The mean  $SpO<sub>2</sub>$  showed a significant  $(p=0.003)$  increase upon follow-up, i.e., the mean baseline  $SpO<sub>2</sub>$  preoperatively was insignificantly different compared with reading after induction, at 10 min, 20 min, and 30 min. It was significantly lower than the readings at the end of the procedure. We followed Friedrich et al.  $[20]$ , who reported that baseline oxygen saturation ranged from 91–100 with a mean  $+$  SD of 98  $+$  2.

In the current study, the mean  $pH$  and  $PO<sub>2</sub>$ were higher preoperatively than postoperative levels  $(p<0.001)$ . In opposition, the mean PaCO2, HCO3, and SaO2 levels preoperatively were significantly lower than the postoperative level (p<0.001). For the total propofol dose in the present study, 42%, 33.3%, and 24.7 % of patients received 400, 500, and 600/800 mg, respectively. According to the RSS, 23 cases were anxious or restless or both, 105 were cooperative and oriented, while 22 cases responded to commands. The patient satisfaction showed that the majority of cases were very satisfied (41%) or satisfied (47%), the minority were neutral (9%), and only three cases (2%) were unsatisfied.

In line with our results, Deitch et al. [22] found that the mean total propofol dose was  $1.40 \pm 43$  mg/kg while the median Ramsey score was 4 (90 sec after the last dose of preprocedural medication). Furthermore, the median time from the first dose of medication to return to baseline alertness was 13 min.

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Our results revealed poor reliability tests for using non-invasive  $CO<sub>2</sub>$  monitoring (Dual-Guard Device) as a substitute for the invasive method (ABG). There was a statistically considerable difference between the two modalities after induction of sedation and at the end  $(p<0.001)$ , i.e., the  $CO<sub>2</sub>$  was significantly higher with ABG compared with DGD. Moreover, Jopling et al.  $[23]$ reported that capnographic use reduced the odds of death among inpatients by 47% and reduced the drug rescue events for outpatients by 61%. However, all techniques were combined, and there were no separate recordings for upper endoscopies.

Saunders et al.  $[24]$  concluded that adding capnography reduced the percentages of adverse events throughout moderate and deep sedation by 18.0 % and 27.2 %, respectively. They reported considerable reductions in both desaturation and apnea with capnographic monitoring. However, the findings of our study were controversial with Barnett et al. <sup>[18]</sup>, who reported that moderate sedation for colonoscopy is a low-risk technique, and adding  $E<sub>1</sub>CO<sub>2</sub>$  monitoring did not ameliorate patient safety or satisfaction. They also suggested that  $EtCO<sub>2</sub>$  might be restrained for patients with a high risk of respiratory complications.

**Limitations:** it was a one-centre trial with a comparatively small sample size and short follow-up time. Only a few studies were available to review non-invasive  $CO<sub>2</sub>$ monitoring in ERCP with the Dual-Guard device (DGD). Several of these studies had small sample sizes.

**Conclusions:** Our study revealed the poor reliability of non-invasive  $CO<sub>2</sub>$  monitoring (using a Dual-Guard Device) compared to the standard invasive method with arterial blood gas analysis (ABG) during conscious sedation for adult ERCP patients. The CO<sup>2</sup> levels were significantly higher with ABG compared to DGD preoperatively and postoperatively

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