## A new device for monitoring end-tidal carbon dioxide during light sedation in surgical procedures

Monitoring end-tidal carbon dioxide (EtCO<sub>2</sub>) during sedation is a critical practice to ensure patient safety. Capnography is a non-invasive monitoring method that measures EtCO<sub>2</sub> and provides information about metabolic, circulatory, and respiratory activities. EtCO<sub>2</sub> monitoring can be an early indicator of airway compromise and allow for early detection of critical respiratory incidents. Ventilation monitoring, through capnography, may provide an element of safety for early and more reliable detection of hypoventilation in patients undergoing sedation for gastrointestinal procedure procedures outside of the operation room.<sup>2</sup>

The role of ETCO<sub>2</sub> monitoring during sedation is still debated. In a study evaluating the effect of different oxygen flow rates on non-invasive CO<sub>2</sub> monitoring, in spontaneously breathing patients undergoing moderate sedation for endoscopic procedures, EtCO<sub>2</sub> differences between the studied groups were statistically significant at preoperative, induction, 5, 10, 20, and 30 minutes but without clinical significance or adverse outcomes.<sup>3</sup> Another study evaluating EtCO<sub>2</sub> monitoring during colonoscopy under moderate sedation found that adding EtCO<sub>2</sub> did not improve safety or patient satisfaction but increased cost.<sup>3</sup>

These data suggest that routine capnography during sedation in spontaneously breathing patients may not be cost-effective and that EtCO<sub>2</sub> may be reserved for patients at higher risk of adverse events.<sup>4</sup> Although this, European and American guidelines for procedural sedation in adult patients strongly recommend the use of capnography as an additional vital parameter to improve patient safety.<sup>5,6</sup> Even the Good Clinical Practices of the Società Italiana Anestesia, Analgesia, Rianimazione e Terapia Intensiva (SIAARTI) for sedation in digestive endoscopy recommend the use of capnography together with monitoring of vital parameters.<sup>7</sup>

Recently, several devices have been developed to evaluate EtCO<sub>2</sub> during sedation. One of these is the Wei cannula, <sup>8</sup> a device equipped with an operating lumen and a lumen dedicated to jet-ventilation through which it is also possible to measure the ETCO<sub>2</sub>. <sup>9</sup> Wei's cannula, which has been scientifically validated mainly in the procedure of bronchoscopy carried out in sedation, has been proved to be an effective device for managing oxygenation of the patient subjected to moderate sedation. <sup>8</sup> The Deaflux (DEAS Co., Castelbolognese, RA, Italy) cannula, evaluated in this report, is different from the Wei cannula. It is equipped with a central lumen (operative/ventilation), another lumen in the cannula wall dedicated to the instillation of drugs, and a rotating hake positioned at the nostril of the patient to detect EtCO<sub>2</sub>.

Here, we attempt to evaluate the efficiency of the Deaflux cannula in monitoring  ${\rm EtCO}_2$  in surgical procedure under light to moderate sedation.

**Materials and methods:** The study protocol was approved by the internal Ethics Committee and conducted in accordance with the principles of the Declaration of Helsinki (Federico II Ethical Committee, approval No. 113/19, March 26, 2019). Written informed consent was obtained from all patients. We enrolled twenty male patients between 18 to 65 years, scheduled for knee arthroplasty under regional anesthesia and light to moderate sedation. Exclusion criteria were American Society of Anesthesiology physical status<sup>4</sup> 3 to 5; inability to provide informed consent, severe pulmonary disease, obstructive sleep apnea syndrome, history of cognitive impairment or disability history of allergy to local and general anesthetic drugs, body mass index more than 35 kg/m², and Mallampati score 4.4

In the operating room, intravenous access was established in the

upper limb and data for oxygen saturation, heart rate, noninvasive blood pressure, respiratory rate, EtCO<sub>2</sub> and the baseline were obtained via multiparameter monitoring. A 22-gauge arterial catheter was introduced into the radial artery under local anesthesia for blood gas analysis after a modified Allen's test. EtCO<sub>2</sub> monitoring was continuously performed using Deaflux cannula. The sampling line of EtCO<sub>2</sub> was connected to the rotating hake positioned at the nostril of each patient and a capnograph displayed the time-based CO<sub>2</sub> graphic waveform, the numerical partial pressure of CO<sub>2</sub> (PaCO<sub>2</sub>), and the derived respiratory rate.

The aim of this study was to evaluate the efficacy of Deaflux cannula in assessing the level of  ${\rm EtCO}_2$  and their concordance with  ${\rm PaCO}_2$  obtained from blood gas analysis. Sedation was carried out by anesthesiologists. All patients received a continuous infusion on propofol with a target level of sedation between Richmond Agitation Sedation Scale (RASS)<sup>4</sup> of 0 and -2. Continuous  ${\rm EtCO}_2$  (numeric and waveform), oxygen saturation, and  ${\rm PaCO}_2$  through blood gas analysis were obtained.

**Statistical analysis:** SPSS version 20.0 software (IBM Corp., Armonk, NY, USA) was used for statistical analysis. Continuous variables are presented as the mean and standard deviation. Categorical variables are shown as the number and percentage unless otherwise indicated. Bland-Altman analysis was used in analyzing the agreement between ETCO<sub>2</sub> and PaCO<sub>2</sub>.

Analysis of receiver operating characteristic curves and dot diagrams was performed with the MedCalc software Version 11.5.1 (Medcalc Software Ltd., Ostend, Belgium). Statistical significance of the area under the receiver operating characteristic curves was calculated against the null hypothesis area under the receiver operating characteristic curves = 0.5.

Results: Twenty patients undergoing knee arthroplasty under regional anesthesia and moderate sedation were consecutively enrolled from September 2022 to February 2023 at University of Naples Federico II. Each patient was kept at a RASS score between 0 and –2 during surgery. Oxygen flows were delivered between zero and 3 L/minute. Cannula insertion was easy in 19 patients while only 1 patient needed an additional dose of local anesthetic to facilitate cannula insertion. Table 1 describes the characteristics of included patients.

The mean value of EtCO<sub>2</sub> measured at the nostril was  $38.6 \pm 6.4$ ; while the mean value of PaCO<sub>2</sub> measured at arterial blood gas analysis was  $42.3 \pm 5.4$ .

Table 1: Characteristics of included patients $(n = 19)$	
Item	Data
Age $(\bar{x}\pm s, yr)$	58±5
Gender (male/female)	17/2
American Society of Anesthesiology physical status	
1	0
2	15
3	4
Richmond agitation sedation scale	
0	9
-1	4
-2	6
Duration of surgery $(\bar{x}\pm s, \min)$	117±24

The analysis of the receiver operating characteristic (ROC) curve, obtained by setting PaCO<sub>2</sub> as the gold reference standard and EtCO<sub>2</sub> as the experimental parameter to be evaluated, showed a prediction of the EtCO<sub>2</sub> measured through the cannula of 78%, meaning that the CO<sub>2</sub> measured through the cannula predicts 78% of the values that could be found in arterial blood gas analysis (**Figure 1A**).



The Bland-Altman analysis, which shows the concordance between PaCO, and EtCO, values measured at the cannula, showed a good concordance of the parameters, reinforcing the evidences that the EtCO, offered by the DEAS cannula is very similar to the PaCO, measured at the arterial line (Figure 1B). Painful removal of the cannula, bleeding in the nostril, desaturation, and the need for additional maneuvers did not occur in any patient.

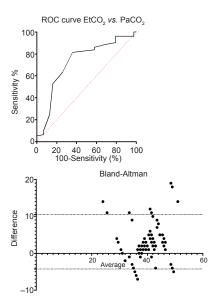


Figure 1: ROC curve and Bland-Altman analysis between end-tidal CO<sub>2</sub> (EtCO<sub>2</sub>) and partial arterial CO, (PaCO,).

Note: (A) ROC curve: Analysis of the ROC curve obtained by setting PaCO, as the gold reference standard and EtCO2 as the experimental parameter to be evaluated. (B) Bland-Altman analysis: Bland-Altman analysis for the concordance between EtCO, and PaCO, X-axis is the average of readings between EtCO, and PaCO, with ±2SD lines (Confidence Interval or CI) parallel to the mean difference line. Y-axis is the difference between paired readings of EtCO2 and PaCO2. Dots are the number of observation performed. ROC: Receiver operating characteristic curve.

Discussion: Nasal cannulas are rarely evaluated for efficacy in scientific literature. 10 The present study evaluated the efficacy of a new nasal cannula in terms of concordance between EtCO2 and PaCO2.

Indeed, we found that this new device for oxygenation and ETCO<sub>2</sub> monitoring, the Deaflux cannula, may be a suitable device for managing patient in mild to moderate sedation. Deaflux cannula showed a predictability of EtCO, measured at the level of the nostril of 78%, which indicates that EtCO, measured through the cannula, predicts to 78% the values of PaCO<sub>2</sub>. The Bland-Altman analysis showed a good agreement of the parameters showing that the reading of the EtCO, offered by the Deaflux cannula is very similar to the PaCO, measured by arterial blood gas. This result is in line with literature that showed a close correlation between the values of EtCO, and PaCO, within few millimeters of Hg.10

Different studies suggested that EtCO, monitoring could identify ventilatory dysfunction in patients at risk of respiratory failure. 11-13 Miner et al.<sup>14</sup> used capnography to detect the presence of respiratory depression and reported that capnography could provide an early warning of ventilatory abnormalities, alerting physicians to respiratory depression before the onset of a hypoxic event. In a recent meta-analysis, Waugh et al. 15 concluded that respiratory events were 17.6 times more likely to be detected if capnography was used. Even the American society of Anesthesiology emphasized the importance of monitoring EtCO, during sedation to assess the adequacy of ventilation.6

In this view, Deaflux canula may be a useful device for two interrelated features. Deaflux cannula allows the measurement of EtCO, at the nostril and the administration of supplemental oxygen during

the sedation.<sup>15</sup> Furthermore, in case of respiratory depression, this cannula may be used to read the decreased level of EtCO, and to deliver rescue doses of oxygen according to patient's needs.

Conclusion: Deaflux cannula allows accurate monitoring of EtCO, during surgical procedure under light to moderate sedation while administering additional level of oxygen flow.

The authors have no conflict of interests with Deaflux.

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