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ASSESSMENT OF A NOVEL REUSABLE 3D-PRINTED DUAL $ETCO_2$–O_2 UNIVERSAL ADAPTER FOR END-TIDAL CARBON DIOXIDE MONITORING DURING REGIONAL ANAESTHESIA:A PROSPECTIVE COMPARATIVE CROSSOVER STUDY

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ABSTRACT

Objective: Capnography is an important method for continuous monitoring of ventilation during anaesthesia and procedural sedation. However, reliable end-tidal carbon dioxide ($EtCO_2$) monitoring in spontaneously breathing patients receiving oxygen through a conventional face mask can be difficult. This study evaluated the clinical performance of a novel reusable three-dimensional (3D)-printed dual $EtCO_2$–O_2 universal adapter designed for use with a standard Hudson mask.

Materials & Methods: This prospective comparative crossover study was conducted among 60 adult patients undergoing elective surgery under regional anaesthesia with spontaneous ventilation. $EtCO_2$ measurements were recorded using the novel reusable 3D-printed adapter and the commercially available Sumi Hi-Capno Facemask under identical clinical conditions. Arterial partial pressure of carbon dioxide ($PaCO_2$) was used as the reference standard. The primary outcome was $EtCO_2$ measurement accuracy. Secondary outcomes included $PaCO_2$–$EtCO_2$ gradient, Bland–Altman agreement, waveform quality, clinical feasibility, and cost profile.

Results: The mean arterial $PaCO_2$ was 39.78 ± 2.91 mmHg. The mean $EtCO_2$ was 37.89 ± 2.98 mmHg with the novel adapter and 37.68 ± 3.34 mmHg with the Sumi Hi-Capno Facemask. The mean $PaCO_2$–$EtCO_2$ gradient was 1.89 ± 1.46 mmHg for the novel adapter and 2.10 ± 1.77 mmHg for the Sumi Hi-Capno Facemask, with no significant difference between devices. Bland–Altman analysis showed acceptable agreement with $PaCO_2$. Successful waveform acquisition was achieved in all patients.

Discussion and conclusion: The novel reusable 3D-printed dual $EtCO_2$–O_2 adapter demonstrated $EtCO_2$ measurement accuracy, agreement with $PaCO_2$, waveform quality, and clinical feasibility comparable to the Sumi Hi-Capno Facemask. Its reusable design may provide a cost-effective alternative for routine capnographic monitoring during regional anaesthesia, especially in resource-limited settings.

KEYWORDS: Capnography; End-tidal carbon dioxide; $EtCO_2$; Regional anaesthesia; 3D printing; Hudson mask; Sumi Hi-Capno Facemask; Bland–Altman analysis.

INTRODUCTION

Capnography has become an indispensable component of modern perioperative monitoring because it provides continuous, non-invasive assessment of ventilation through measurement of end-tidal carbon dioxide ($EtCO_2$). In contrast to pulse oximetry, which primarily reflects oxygenation and may remain within the normal range despite significant hypoventilation in patients receiving supplemental oxygen, capnography enables early recognition of respiratory depression, airway obstruction, apnea, and ventilatory failure before clinically significant oxygen desaturation occurs. Consequently, continuous $EtCO_2$ monitoring has become an important patient safety measure during anesthesia, procedural sedation, and postoperative recovery. (1–3)

Professional societies, including the American Society of Anesthesiologists (ASA), recommend continuous monitoring of ventilation using capnography during general anaesthesia and moderate or deep procedural sedation whenever feasible. These recommendations are supported by evidence demonstrating that capnography identifies respiratory compromise earlier than routine clinical observation or pulse oximetry alone, allowing timely intervention and reducing the incidence of adverse respiratory events.(4-6) However, despite these recommendations, routine $EtCO_2$ monitoring in spontaneously breathing patients remains inconsistent, particularly during regional anaesthesia where oxygen is commonly delivered using conventional face masks.

The Hudson mask is one of the most widely used oxygen delivery devices during regional anaesthesia because of its simplicity, availability, and patient comfort. Nevertheless, conventional Hudson masks do not permit simultaneous oxygen delivery and reliable sampling of exhaled carbon dioxide. The Sumi Hi-Capno Face Mask has been developed to facilitate

simultaneous oxygen administration and $EtCO_2$ monitoring by incorporating a dedicated sidestream carbon dioxide sampling port into the face mask design. Although these devices demonstrate satisfactory clinical performance, they are predominantly single-use, relatively expensive, and may not be readily available in resource-constrained healthcare settings. These practical limitations restrict widespread implementation of continuous capnographic monitoring despite established clinical benefits. (7-9)

Recent advances in three-dimensional (3D) printing have created new opportunities to develop low-cost, customised medical devices through rapid manufacturing and excellent adaptability to existing clinical equipment. Medical-grade 3D printing enables the production of reusable components that can be sterilised and integrated with standard oxygen delivery systems without requiring major modifications to existing infrastructure. In anaesthesiology, 3D-printed devices have shown promising applications in airway management, simulation training, and patient-specific procedural planning, demonstrating acceptable feasibility, precision, and safety following appropriate validation.(10-12)

To address the limitations of existing oxygen delivery interfaces, a novel reusable dual $EtCO_2$–O_2 universal adapter was developed using 3D-printing technology for integration with a standard Hudson mask. The adapter incorporates a dual-channel design that enables uninterrupted oxygen delivery while positioning the carbon dioxide sampling port close to the patient's airway to facilitate efficient collection of expired gas. This design aims to provide accurate $EtCO_2$ monitoring without compromising oxygen administration, while offering a reusable and economically sustainable alternative to the Sumi Hi-Capno Facemask, a commercially available disposable capnography facemask."

Although the proposed adapter was developed to improve accessibility and affordability of capnographic monitoring, its clinical utility depends on demonstrating measurement accuracy comparable with established commercial monitoring systems. Device validation studies require assessment of agreement with accepted monitoring devices and evaluation of correlation with arterial partial pressure of carbon dioxide ($PaCO_2$), the reference standard for carbon dioxide measurement. Statistical techniques such as correlation analysis and Bland–Altman agreement analysis are widely recommended for determining whether a novel monitoring device can be considered clinically interchangeable with existing technologies.

Therefore, this prospective comparative study was undertaken to evaluate the performance of a novel 3D-printed reusable dual $EtCO_2$–O_2 universal adapter integrated with a standard Hudson mask by comparing its end-tidal carbon dioxide measurements with those obtained using the Sumi Hi-Capno Facemask, a commercially available capnography facemask, in spontaneously breathing patients undergoing regional anaesthesia. The agreement of both devices with arterial partial pressure of carbon dioxide ($PaCO_2$), along with waveform quality, clinical feasibility, and cost profile, was also evaluated.

MATERIALS AND METHODS

Study design and setting

This prospective comparative crossover study was conducted in the Department of Anaesthesiology, Saveetha Medical College and Hospital, Saveetha Institute of Medical and Technical Sciences (SIMATS), Chennai, India, over a period of one year after obtaining approval from the Institutional Ethics Committee (IEC Reference No. 013/11/2024/IEC/SMCH). Written informed consent was obtained from all participants before enrolment.

Study participants

Adult patients aged 18–50 years with American Society of Anesthesiologists (ASA) physical status I or II who were scheduled for elective surgery under regional anaesthesia and maintained on spontaneous ventilation were consecutively recruited. Patients with a history of smoking, bronchial asthma, chronic obstructive pulmonary disease, obstructive sleep apnoea, obesity, haemodynamic instability, sepsis, hypothermia, intraoperative opioid administration, anticipated requirement for endotracheal intubation, surgical duration of less than one hour, or refusal to participate were excluded.

Sample size estimation

The sample size was calculated using the comparison of means based on a previously published study evaluating end-tidal carbon dioxide ($EtCO_2$) measurements using a Capnoxygen™ mask and a nasal cannula. The estimated minimum sample size was 55 participants. To compensate for possible dropouts and improve the robustness of agreement analyses, 60 participants were included in the study. Eligible patients were enrolled using consecutive sampling.

Study devices

The investigational device was a novel reusable three-dimensional (3D)-printed dual $EtCO_2$–O_2 universal adapter designed for integration with a standard Hudson mask. The adapter incorporated a dual-channel coaxial configuration with separate lumens for oxygen delivery and sidestream carbon dioxide sampling. The sampling port was positioned between the nose and mouth to optimize collection of expired gas while minimizing dilution by supplemental oxygen. Before clinical evaluation, the device underwent dimensional verification, leak testing, oxygen flow validation, and simulated capnography testing. The device was designed for repeated use following validated sterilisation procedures.

The comparator was the Sumi Hi-Capno Facemask (Life Tech India Pvt. Ltd., Chennai, Tamil Nadu, India) a commercially available disposable capnography facemask designed for simultaneous oxygen delivery and sidestream end-tidal carbon dioxide ($EtCO_2$) monitoring in spontaneously breathing patients.

Study procedure

Following successful administration of regional anaesthesia, a standard Hudson mask was applied, and supplemental oxygen was administered at a flow rate of 5 L/min. After a stabilisation period of 5 minutes, arterial blood was collected for arterial blood gas (ABG) analysis to determine the arterial partial pressure of carbon dioxide ($PaCO_2$).

Each participant underwent sequential end-tidal carbon dioxide ($EtCO_2$) monitoring using the novel reusable three-dimensional (3D)-printed dual $EtCO_2$–O_2 universal adapter and the Sumi Hi-Capno Facemask under identical clinical conditions. The order of device application was kept uniform for all participants to ensure consistency in measurements. For each device, $EtCO_2$ values were recorded at 2-minute intervals over a period of 10 minutes, yielding five consecutive measurements. The mean $EtCO_2$ value obtained from these five readings was used for statistical analysis.
A 2-minute washout period was maintained between the two monitoring sessions to minimize potential carry-over effects. Throughout the study, demographic characteristics, baseline physiological parameters, arterial $PaCO_2$ values, $EtCO_2$ measurements, capnographic waveform quality, and device feasibility were documented. All measurements were obtained while patients remained spontaneously breathing under regional anaesthesia without alteration of oxygen flow or monitoring conditions. The total monitoring time for each participant was approximately 30 minutes.

Outcome measures
The primary outcome was the accuracy of end-tidal carbon dioxide ($EtCO_2$) measurement obtained using the novel reusable three-dimensional (3D)-printed dual $EtCO_2$–O_2 universal adapter compared with the Sumi Hi-Capno Facemask, using arterial partial pressure of carbon dioxide ($PaCO_2$) as the reference standard.
The secondary outcomes included the $PaCO_2$–$EtCO_2$ gradient, correlation between $EtCO_2$ and $PaCO_2$ measurements, agreement between $EtCO_2$ and $PaCO_2$ assessed using Bland–Altman analysis, capnographic waveform quality, device feasibility during regional anaesthesia, and the comparative cost of the two monitoring systems.

Statistical analysis
Data were analysed using IBM SPSS Statistics for Windows, Version 26 (IBM Corp., Armonk, NY, USA). Continuous variables are presented as mean ± standard deviation (SD), whereas categorical variables are expressed as frequency and percentage. The normality of continuous variables was assessed using the Shapiro–Wilk test. Paired comparisons between the novel reusable 3D-printed dual $EtCO_2$–O_2 universal adapter and the Sumi Hi-Capno Facemask were performed using the paired Student's t-test. Correlation between $EtCO_2$ and arterial partial pressure of carbon dioxide ($PaCO_2$) was assessed using Pearson's correlation coefficient (r). Agreement between $EtCO_2$ measurements and arterial $PaCO_2$ was evaluated using Bland–Altman analysis, and the mean bias with 95% limits of agreement (LoA) was calculated. A two-tailed P value of <0.05 was considered statistically significant.

RESULTS

Table 1. Baseline demographic and clinical characteristics of the study participants (n = 60)

Characteristic	Mean ± SD
Age (years), mean ± SD	32.97 ± 7.90
Age, median (range)	33.0 (18–50)
Sex, n (%)	
Male	33 (55.0)
Female	27 (45.0)
Body mass index (kg/m²)	24.32 ± 2.72
Body mass index, median (range)	24.60 (19.0–29.5)
BMI category, n (%)	
Normal (18.5–24.9 kg/m²)	34 (56.7)
Overweight (25.0–29.9 kg/m²)	26 (43.3)
ASA physical status, n (%)	
ASA I	30 (50.0)
ASA II	30 (50.0)
Pulse rate (beats/min)	75.87 ± 7.60
Systolic blood pressure (mmHg)	120.67 ± 9.79
Diastolic blood pressure (mmHg)	79.50 ± 5.95
Arterial $PaCO_2$ (mmHg)	39.78 ± 2.91

Values are presented as mean ± standard deviation (SD), median (range), or number (percentage).
A total of 60 spontaneously breathing patients undergoing elective surgery under regional anaesthesia were included in the study. The mean age of the participants was 32.97 ± 7.90 years, with a median age of 33 years (range, 18–50 years). The study population comprised 33 (55.0%) males and 27 (45.0%) females. The mean body mass index was 24.32 ± 2.72 kg/m², with 56.7% of participants classified as having normal BMI and 43.3% as overweight. Equal proportions of patients belonged to ASA physical status I and II (50% each). Baseline haemodynamic parameters were stable, with a mean pulse rate of 75.87 ± 7.60 beats/min, mean systolic blood pressure of 120.67 ± 9.79 mmHg, mean diastolic blood pressure of 79.50 ± 5.95 mmHg, and mean arterial $PaCO_2$ of 39.78 ± 2.91 mmHg.

Table 2. Comparison of end-tidal carbon dioxide ($EtCO_2$) measurements obtained using the novel adapter and Sumi Hi-Capno Facemask with arterial $PaCO_2$ (n = 60)

Variable	Novel Adapter	Sumi Hi-Capano facemask	Arterial $PaCO_2$	P value
Mean $EtCO_2$ (mmHg)	37.89 ± 2.98	37.68 ± 3.34	39.78 ± 2.91	<0.001†
Median$EtCO_2$ (mmHg)	37.70	37.45	39.45	—
Range (mmHg)	33.1–44.5	31.0–43.3	35.0–45.4	—
Mean $PaCO_2$–$EtCO_2$gradient (mmHg)	1.89 ± 1.46	2.10 ± 1.77	—	0.281‡
Median gradient (mmHg)	1.65	2.00	—	—
Gradient range (mmHg)	−1.4 to 5.2	−1.6 to 6.0	—	—

† Comparison between arterial $PaCO_2$ and $EtCO_2$ values.
‡ Comparison of the $PaCO_2$–$EtCO_2$ gradients between the novel adapter and Sumi Hi -Capno facemask
The mean $EtCO_2$ measured using the novel reusable adapter was 37.89 ± 2.98 mmHg, while the corresponding value obtained using Sumi Hi-Capno facemask was 37.68 ± 3.34 mmHg. The mean arterial $PaCO_2$ was 39.78 ± 2.91 mmHg. Both monitoring systems demonstrated $EtCO_2$ values slightly lower than arterial $PaCO_2$, which is consistent with the expected physiological $PaCO_2$–$EtCO_2$ gradient. The mean $PaCO_2$–$EtCO_2$ gradient was 1.89 ± 1.46 mmHg for the novel adapter and 2.10 ± 1.77 mmHg for Sumi Hi-Capno Facemask, with no statistically significant difference between the two devices (P = 0.281).

Table 3. Bland–Altman agreement analysis of the novel adapter and Sumi Hi -Capno facemask (n = 60)

Comparison	Mean bias (mmHg)	SD of difference	Lower limit of agreement (95% LoA)	Upper limit of agreement (95% LoA)
Novel adapter vs arterial $PaCO_2$	−1.89	1.4564	−4.7445	0.9645
Sumi Hi -Capno facemask vs arterial $PaCO_2$	−2.10	1.7656	−5.5572	1.3639
Novel adapter vs Sumi Hi -Capno facemask	0.2117	2.3047	−4.3055	4.7288

Bias was calculated as $EtCO_2$ − $PaCO_2$ for comparisons with the reference standard and as Novel adapter $EtCO_2$ − Sumi Hi-Capno Facemask $EtCO_2$ for the inter-device comparison.
Bland–Altman analysis demonstrated good agreement between both monitoring systems and the reference standard (arterial $PaCO_2$). The novel adapter showed a mean bias of −1.89 mmHg with 95% limits of agreement ranging from −4.74 to 0.96 mmHg, whereas Sumi Hi-Capno Facemask demonstrated a mean bias of −2.10 mmHg with limits of agreement from −5.56 to 1.36 mmHg. Direct comparison between the novel adapter and Sumi Hi -Capno facemask revealed a minimal mean bias of 0.21 mmHg, with 95% limits of agreement between −4.31 and 4.73 mmHg, indicating excellent agreement and no clinically significant systematic difference between the two monitoring systems.

Table 4. Clinical performance of the novel adapter and Sumi Hi -Capno facemask (n = 60)

Parameter	Novel Adapter	Sumi Hi -Capno facemask	P value
Successful capnographic waveform acquisition, n (%)	60 (100)	60 (100)	1.000
Waveform quality – Excellent, n (%)	58 (96.7)	57 (95.0)	0.648
Waveform quality – Acceptable, n (%)	2 (3.3)	3 (5.0)	
Failure to obtain interpretable waveform, n (%)	0 (0.0)	0 (0.0)	—
Successful integration with Hudson mask, n (%)	60 (100)	60 (100)	1.000
Device-related complications, n (%)	0 (0.0)	0 (0.0)	—

Values are presented as numbers (percentages). The cost comparison is descriptive because the objective was to demonstrate the practical advantage of the reusable adapter rather than to perform a formal economic evaluation.

Both monitoring systems demonstrated excellent clinical performance during regional anaesthesia. A capnographic waveform was successfully obtained in all participants using both devices. The proportion of excellent-quality waveforms was comparable between the novel adapter (96.7%) and Sumi Hi-Capno facemask (95.0%), with no statistically significant difference (P = 0.648). Both devices were successfully integrated with the Hudson mask in all patients, and no device-related complications or monitoring failures were encountered during the study. In addition, the novel reusable adapter offered a substantially lower estimated cost per use than the commercially available disposable interface, highlighting its potential economic advantage in routine clinical practice.

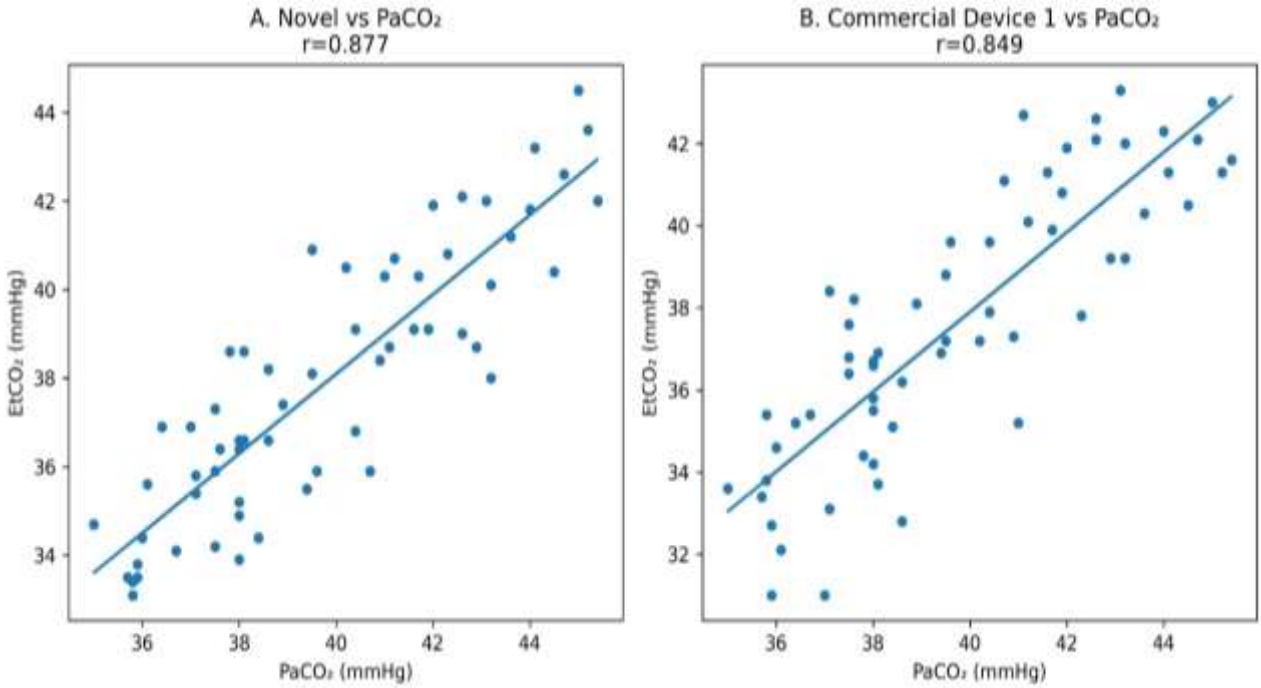

Figure 1. Correlation between end-tidal carbon dioxide ($EtCO_2$) measurements and arterial partial pressure of carbon dioxide ($PaCO_2$).

(A) Scatter plot demonstrating the correlation between $EtCO_2$ measured using the novel reusable dual $EtCO_2$–O_2 adapter and arterial $PaCO_2$.

(B) Scatter plot demonstrating the correlation between $EtCO_2$ measured using Commercial Device 1 (Sumi Hi -Capno facemask) and arterial $PaCO_2$.

The solid line represents the linear regression line, illustrating the strong positive correlation between $EtCO_2$ and $PaCO_2$ measurements in spontaneously breathing patients undergoing regional anaesthesia.

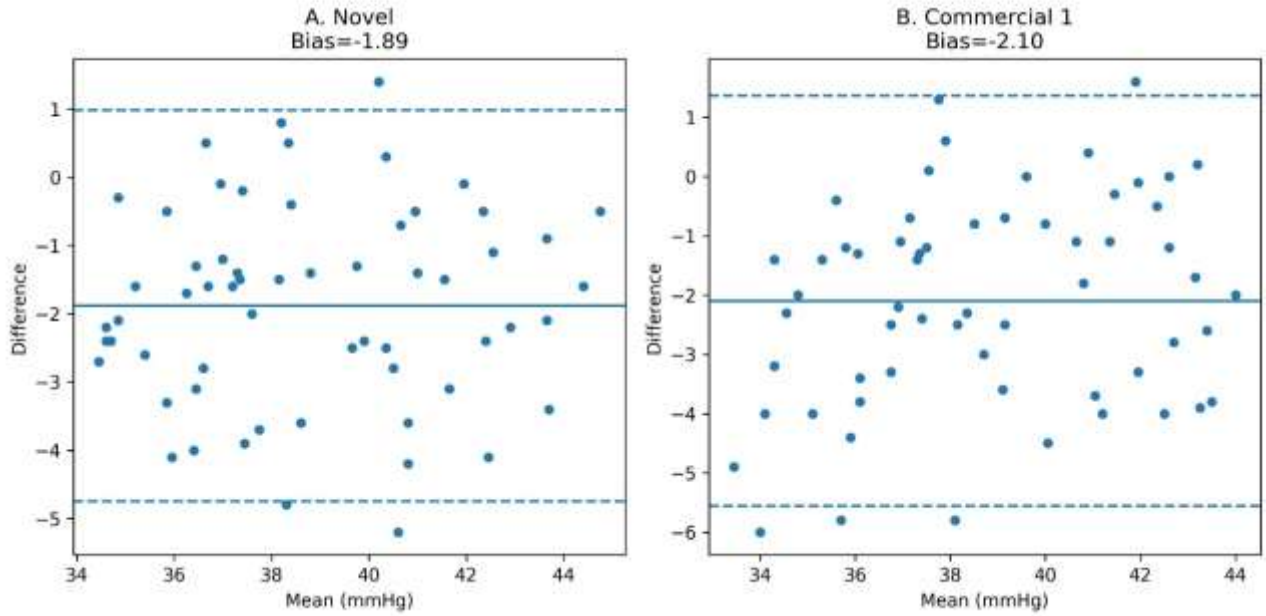

Figure 2. Bland–Altman analysis demonstrating agreement between end-tidal carbon dioxide ($EtCO_2$) measurements and arterial partial pressure of carbon dioxide ($PaCO_2$).

Description (Figure legend):
(A) Bland–Altman plot showing the agreement between $EtCO_2$ measured using the novel reusable dual $EtCO_2$–O_2 adapter and arterial $PaCO_2$.
(B) Bland–Altman plot showing the agreement between $EtCO_2$ measured using Commercial Device 1 (Sumi Hi -Capno facemask) and arterial $PaCO_2$.
The central solid line represents the mean bias, while the upper and lower dashed lines indicate the 95% limits of agreement (mean bias ± 1.96 SD). Most observations lie within the limits of agreement, indicating clinically acceptable agreement between $EtCO_2$ and arterial $PaCO_2$ measurements.

DISCUSSION

The present study demonstrated that the novel reusable three-dimensional (3D)-printed dual $EtCO_2$–O_2 universal adapter provided end-tidal carbon dioxide ($EtCO_2$) measurements comparable to those obtained using the Sumi Hi-Capno Facemask in spontaneously breathing patients undergoing regional anaesthesia. Both devices showed similar mean $EtCO_2$ values, comparable $PaCO_2$–$EtCO_2$ gradients, excellent agreement with arterial $PaCO_2$, and high-quality capnographic waveforms. These findings indicate that the novel adapter can reliably monitor ventilation while offering the additional advantages of reusability and potential cost savings.

Continuous capnographic monitoring is increasingly recommended for spontaneously breathing patients receiving anaesthesia or procedural sedation because it enables early detection of hypoventilation before clinically significant oxygen desaturation occurs. However, obtaining reliable $EtCO_2$ measurements during oxygen administration remains challenging because supplemental oxygen may dilute expired carbon dioxide and reduce sampling accuracy. Dedicated capnography face masks have been developed to overcome these limitations by facilitating simultaneous oxygen delivery and carbon dioxide sampling. The findings of the present study are consistent with previous reports demonstrating that mask-based capnography provides clinically reliable $EtCO_2$ measurements with acceptable agreement with arterial $PaCO_2$ in non-intubated patients.(13-15)

In the present study, the mean $PaCO_2$–$EtCO_2$ gradient was approximately 2 mmHg for both devices, with no statistically significant difference between the novel adapter and the Sumi Hi-Capno Facemask. This gradient is within the range reported in previous studies evaluating $EtCO_2$ monitoring in spontaneously breathing patients and reflects the expected physiological difference between arterial and end-tidal carbon dioxide measurements. Although $EtCO_2$ cannot replace arterial blood gas analysis for absolute carbon dioxide estimation, it remains a valuable non-invasive tool for continuous assessment of ventilatory trends and early recognition of respiratory compromise.(13,16)

Method comparison studies should evaluate both correlation and agreement, as a high correlation alone does not necessarily indicate clinical interchangeability. Therefore, Bland–Altman analysis was performed to assess the agreement between $EtCO_2$ measurements and arterial $PaCO_2$. The novel reusable adapter demonstrated a slightly lower mean bias and narrower limits of agreement than the Sumi Hi-Capno Facemask, indicating that its measurements closely approximated the reference standard. Although minor differences between $EtCO_2$ and $PaCO_2$ are physiologically expected because of alveolar dead space, the observed bias in the present study was clinically acceptable and comparable with that reported for commercially available capnography interfaces. These findings support the reliability of the novel adapter for routine perioperative ventilation monitoring.(17-19)

Both devices also demonstrated excellent clinical performance, with successful capnographic waveform acquisition in all participants and no device-related complications. The quality of the capnographic waveform obtained using the novel adapter was comparable to that of the Sumi Hi-Capno Facemask, suggesting that the dual-channel design effectively facilitates simultaneous oxygen delivery and carbon dioxide sampling without compromising signal quality. Reliable waveform acquisition is essential because clinical interpretation of $EtCO_2$ depends not only on numerical values but also on waveform morphology, which enables early recognition of airway obstruction, hypoventilation, and apnea.(20,21)

An important advantage of the novel adapter is its reusable three-dimensional (3D)-printed design, which has the potential to reduce the dependence on disposable capnography interfaces while maintaining comparable monitoring performance. This feature may be particularly beneficial in resource-limited healthcare settings where the recurring cost of single-use devices can limit routine implementation of continuous capnographic monitoring. Nevertheless, the present study evaluated the device in ASA I–II adult patients undergoing elective surgery under regional anaesthesia at a single centre. Further multicentre studies involving larger and more diverse patient populations, including paediatric patients, obese individuals, and patients with pulmonary disease, are required to confirm the generalisability of these findings and to evaluate long-term durability and cost-effectiveness.(22)

In conclusion, the novel reusable 3D-printed dual $EtCO_2$–O_2 universal adapter demonstrated measurement accuracy, agreement with arterial $PaCO_2$, waveform quality, and clinical feasibility comparable to those of the commercially available Sumi Hi-Capno Facemask. The reusable design and lower anticipated cost make it a promising alternative for expanding routine capnographic monitoring during regional anaesthesia and procedural sedation, particularly in resource-constrained healthcare settings.

CONCLUSION

The novel reusable three-dimensional (3D)-printed dual $EtCO_2$–O_2 universal adapter demonstrated measurement accuracy, agreement with arterial $PaCO_2$, capnographic waveform quality, and clinical feasibility comparable to those of the commercially available Sumi Hi-Capno Facemask in spontaneously breathing patients undergoing regional anaesthesia. The reusable design and lower anticipated cost make it a promising alternative for continuous capnographic monitoring, particularly in resource-limited healthcare settings. Further multicentre studies involving larger and more diverse patient populations are warranted to validate these findings and assess long-term clinical applicability.

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