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At-Home End-Tidal Carbon Dioxide Measurement in Children with Invasive Home Mechanical Ventilation

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Abbreviations: bronchopulmonary dysplasia (BPD), Carbon dioxide (CO₂), chronic lung disease (CLD), end-tidal carbon dioxide (EtCO₂), Food and Drug Administration (FDA), home mechanical ventilation (HMV), partial pressure of venous carbon dioxide (PvCO₂), portable endotracheal capnograph (PEC), REDCap (Research Electronic Data Capture), transcutaneous CO₂ (TCM)

Abbreviated title: Validation of At-Home End-Tidal CO₂ Device

Data Availability: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Abstract

Background

Carbon dioxide concentration trending is used in chronic management of children with invasive home mechanical ventilation (HMV) in clinical settings, but options for end-tidal carbon dioxide (EtCO₂) monitoring at home are limited. We hypothesized that a palm-sized, portable endotracheal capnograph (PEC) that measures EtCO₂ could be adapted for in-home use in children with HMV.

Methods

We evaluated the internal consistency of the PEC by calculating an intra-class correlation coefficient of 3 back-to-back breaths by children (0-17 years) at baseline health in clinic. Pearson's correlation was calculated for PEC EtCO₂ values with concurrent mean values of in-clinic EtCO₂ and transcutaneous CO₂ (TCM) capnometers. The Bland-Altman test determined their level of agreement. Qualitative interviews and surveys assessed usability and acceptability by family-caregivers at home.

Results

CO₂ values were collected in awake children in varied activity levels and positions (N=30). The intra-class correlation coefficient for the PEC was 0.95 (p<0.05). The correlation between the PEC and in-clinic EtCO₂ device was 0.85 with a mean difference of -3.8 mmHg and precision of ±1.1 mmHg. The correlation between the PEC and the clinic TCM device was 0.92 with mean difference of 0.2 mmHg and precision of ±1.0.

Family-caregivers (N=10) trialed the PEC at home; all were able to obtain measurements at home while children awake and sometimes asleep.

Conclusions

A portable, non-invasive device for measuring EtCO₂ was feasible and acceptable, with values that trend similarly to currently in-practice, outpatient models. These devices may facilitate monitoring of EtCO₂ at home in children with invasive HMV.

Introduction

Children who require invasive home mechanical ventilation (HMV) via tracheostomy are medically vulnerable patients with high health care use and cost.¹⁻³ The number of pediatric patients benefiting from HMV has grown over the past decades,⁴⁻⁸ and HMV allows affected children to live and grow at home despite the need for ongoing ventilator support. Periodically, the children reliant on HMV are evaluated for readiness to decrease or wean ventilatory support, either by decreasing settings or providing successively longer periods off the ventilator (“breaks”). While no standard process for HMV weaning exists, the published literature does recommend routine clinical monitoring to minimize morbidity and mortality during prolonged HMV use.⁹ Developing approaches to conducting this clinical monitoring and weaning HMV remotely may allow for more efficient and individualized care in a patient-family-centered manner at home.

As an indicator of effective respiration, carbon dioxide (CO₂) is one measurement that is often used by clinicians to monitor the effectiveness of ventilation, along with other data such as oxygenation, measured tidal volume, inspiratory pressure and weight. Since the 1970’s, non-invasive capnographs and capnometers that can measure either end-tidal carbon dioxide (EtCO₂) or transcutaneous CO₂ (TCM) have become increasingly available in the outpatient clinic setting to assist in this objective assessment

as an alternative to more invasive blood gas monitoring.¹⁰ However, reporting of CO₂ monitoring at home has been relatively limited in the literature. Previous work by Liptzin et al showed that weaning children with HMV with close observation was safe in the context of a pediatric respiratory care unit, but reported that intermittent EtCO₂ monitoring was not always feasible.¹¹ Besides Liptzin's work, we are unaware of published studies that explore the use of CO₂ data collection to support weaning in pediatric patients reliant on HMV. Current CO₂ devices seem to require several minutes to calibrate, are sufficiently large to require them to be placed on a stand or table for use, and often are connected to the patient via a wire; characteristics which together limit their use to the clinic setting, thereby requiring patients to go to clinic for weaning evaluations. Because of the challenges with transportation of children with HMV, we were interested in identifying whether there were any alternative portable CO₂ devices that could be tested as a first step in a series of studies to build evidence-based approaches to facilitate proactive HMV weaning at home.

Since Liptzin's published work, a palm-sized, portable endotracheal capnograph (PEC) (EMMA™ capnograph, Masimo, Irvine, CA) has been designed to measure mainstream EtCO₂ when attached in-line directly to an artificial airway during transport or anesthesia.¹² Previous studies of the PEC showed strong correlation (0.87) between PEC EtCO₂ values and partial pressure of venous carbon dioxide (PvCO₂) in 9 hospitalized infants with tracheostomy tubes.¹³ The PEC EtCO₂ values were also compared in anesthetized adults to PaCO₂ and capnometers connected side stream – via tubing connected to the side of the mainstem tubing – with comparative mean values of 29.1 +/- 2.5 mmHg (PEC), 35.1 +/- 3.8 mmHg (PaCO₂), 31.3 +/- 2.4 mmHg (side stream

capnometer).^{14, 15} However, no research has demonstrated its use in awake children at their baseline state of health who rely on invasive HMV in an outpatient setting, whose age may range from infancy to young adulthood and who may have a range of physical activity levels and medical conditions.

Given the PEC's small size, we hypothesized it could be adapted for portable measurement of EtCO₂ at home in lieu of measurement of EtCO₂ or TCM capnometers in clinic. To test this, we performed a pilot study designed to evaluate: 1) the internal consistency of the PEC device EtCO₂ measurement in back-to-back breaths; 2) the correlation and agreement between the PEC and standard clinic EtCO₂ and transcutaneous CO₂ (TCM) capnometers; and 3) the feasibility and usability of parents measuring CO₂ with the PEC in their children reliant on invasive HMV at home.

Methods

Setting and Patient Inclusion

Children receiving HMV were recruited from an independent children's hospital's Pulmonary Habilitation Program which provides longitudinal care for children with a tracheostomy tube receiving HMV. Parent-guardians of eligible patients were approached and provided informed consent. Inclusion criteria were children aged 0-17 years old currently using invasive HMV. Children who would be weaned completely from the ventilator within the next two months or were at end of life were excluded. Given the objective of the project was to confirm the ability to feasibly measure end tidal EtCO₂ in a broad population of children cared for in HMV programs, children were included regardless of their indication for HMV.

The Institutional Review Board approved all study procedures (IRB # 2020-3600). Study data were collected and managed using REDCap (Research Electronic Data Capture) secure electronic data capture tools hosted at Northwestern University.¹⁶

Devices

The PEC used was the EMMA™, a patented Food and Drug Administration (FDA)-approved non-invasive mainstream CO₂ monitor that uses a spectrometer and infrared detector to measure and then display a continuous quantitative EtCO₂ value (0-99 mmHg) and capnogram wave form (0-53mg per 0-7kPa scale), as well as a respiratory rate (3-150 breaths per minute).¹⁷ The PEC device fits a disposable airway adapter (6mL dead space) which can be attached to the end of a patient's endotracheal or tracheostomy tube, which then measures the EtCO₂ from the expired respiratory gas. The device is ~2" x 1.5" x 1.5" and weighs ~2 ounces with two standard AAA batteries that last 6-10 hours; it turns off automatically after 2 minutes if not in use.

We compared the PEC to two clinic devices: (1) a device that measures EtCO₂ and (2) a device that measures TCM, both considered standard-of-care approaches to in-clinic evaluations. The standard clinic EtCO₂ device was a mainstream CAPNOSTAT 5™ sensor and adapter which attaches to the tracheostomy tube, and then connects via a cable to the Respironics NM3 device (Model 7900) that displays quantitative EtCO₂ (0-150 mmHg) and other parameters, including respiratory rate.¹⁸ The clinic TCM device was a Sentec Digital Monitoring System, designed for noninvasive ventilation and oxygenation monitoring, that measures transcutaneous CO₂ tensions (0-200mmHg) using a sensor applied to the skin surface.¹⁹

Data Collection to Assess Feasibility, Consistency, and Correlation with Clinic Models

First, we developed a brief protocol to use the PEC CO₂ measurements in children requiring HMV presenting for routine follow-up care in clinic. The goal was to establish a feasible, reproducible method for PEC EtCO₂ data collection in awake children with HMV, defined as reproducible data collection using the device by any member of the health care team when a child was connected or disconnected from the ventilator. Participants were recruited and consented to participate until a protocol was established (n=9) to ensure a consistent process prior to the larger analysis. The protocol involved turning the PEC on, waiting 15 seconds per manufacturer's instructions, then attaching the PEC adapter inline as close to the tracheostomy as the child's circuit as would allow, and watching for the end-tidal breath waveforms to be displayed across the entire screen. If the child began moving due to the placement of the device, we would allow the child to reposition and acclimatize to the device before taking the reading to ensure its accuracy.

We then conducted CO₂ measurements in additional consented participants to establish agreement and correlation between the PEC and standard EtCO₂ and TCM devices. To assess internal consistency, each measurement was taken three times per device per patient.

Data Collection to Assess Usability

We then evaluated the usability of the PEC in new family-caregiver (parent) end-users, through a user-centered design approach.^{20, 21} After consenting to participate, parents were shown how to use the PEC during an outpatient in-person visit, asked to perform it independently with their child, then asked their initial impressions of the device. Next, the PECs were sent home with parents with instructions to use it while the child was awake, asleep, and, if applicable, at the end of a ventilatory break. Parents met with the interview team remotely from home (Zoom Video Communications, Inc., San

Jose, California) to provide qualitative feedback on the home use experience including their perceptions of its acceptability and usability. Survey items were administered at the initial training session and after use at home using a Likert agreement scale (Strongly disagree (1) to Strongly agree (5)) to assess specific components of usability, including perceived learnability, memorability, and satisfaction including whether the device was acceptable and valued.^{21,22}

Analysis

Descriptive statistics were used to evaluate participant characteristics. Feasibility was assessed by the ability to use the PEC in patients with different activity levels, need to stop measurement due to patient discomfort, frequency of adapter malfunction, and ability to use the device both connected and disconnected to the ventilator.

Internal consistency of the three device readings was summarized using intra-class correlation coefficients. To assess correlation and agreement of the PEC EtCO₂ values with the clinic models, first a Pearson's correlation was used to compare the linear relationship between the mean values of the PEC with the mean clinic EtCO₂ device and the mean clinic TCM model. The Bland-Altman approach was used to determine the level of paired agreement between devices.^{23,24} Bias was defined as the mean difference in values obtained with two different methods of measurement.²⁴ The precision was assessed by the width of 95% confidence interval.²⁴

To assess parents' perceptions of usability, research professionals' written notes and taped recordings were reviewed in real-time manner as feedback was gathered, and user feedback was summarized using rapid qualitative analytic methods.^{25,26} Parents' responses to the Likert scale questions also were analyzed using descriptive statistics.

Results

Participating Patient Characteristics in In-Clinic Comparison

Data were collected from patients (N=30) with a mean age of 4.9 years (SD \pm 4.4, range 1-17), of which 43% were female biological sex, and slightly more than half (N=16, 53%) were of minority race/ethnicity (**Table 1**). Half (N=15, 50%) were on HMV due to CLD from prematurity, and participants had a range of tracheostomy tube sizes ranging from 3.5 to 6.0 mm.

Feasibility

Once a protocol was established, EtCO₂ measurements were obtained with N=30 additional patients in a variety of activity levels and positions (**Table 1**). Measurements were successfully obtained in patients who were both ventilated at the time of measurement (N=21, 70%) or on ventilator break (N=9, 30%). In one case (<1%), the PEC adapter alert alarmed, likely due to secretions blocking the reading window. The adapter was exchanged and there were no further issues. No measurements had to be stopped due to patient discomfort or parental concern. **Figure 1** shows use of the PEC in two different patients, one who is also attached to the tracheostomy tube and ventilator tubing and one in which the PEC is only attached to the tracheostomy tube.

Internal consistency

The intra-class correlation coefficients that compared the 3 back-to-back breaths were 0.95 (p<0.01) for the PEC, 0.98 (<0.01) for the clinic EtCO₂ device, and 0.99 (p<0.01) for the clinic TCM device.

Agreement and Correlation with Clinic Models

The PEC EtCO₂ values across all patients were a mean of 31.4 mmHg (SD 5.6, range 21– 46), compared to clinic EtCO₂ device mean values of 35.1 mmHg (SD 5.6,

range 27 – 47) and clinic TCM device mean values of 31.5 mmHg (SD 6.5, range 22.7 – 53.2).

A scatterplot comparing the PEC EtCO₂ values to the in-clinic EtCO₂ values is shown in **Figure 2a**; the correlation was 0.85. Agreement between the two devices is displayed in the Bland-Altman plot in **Figure 2b**. The mean difference between PEC EtCO₂ and in-clinic EtCO₂ values were -3.8 mmHg (95% CI, -4.9 to -2.7), yielding a precision of ±1.1. One patient (ID#7) was 2 SD outside the limits of agreement with PEC CO₂ values that ranged from 34-35 and clinic End-tidal ranging from 28-30.

A scatterplot comparing the PEC EtCO₂ device to the clinic TCM device is shown in **Figure 3a**; the correlation was 0.92. The agreement between the PEC EtCO₂ values and TCM device is displayed in the Bland-Altman plot in **Figure 3b**. The mean difference between PEC EtCO₂ values and TCM values was 0.2 mmHg (95% CI, -1.2 to 0.8), yielding a precision of ±1.0. Two patients (ID#1 and ID#23) were 2 SD outside the limits of agreement; one patient's PEC CO₂ values ranged from 35-48 and the TCM value of 30.2. The second patient's PEC CO₂ values were 45-47 and TCM was 53.2.

Participating Patient-Family Characteristics in Usability Testing

A total of N=10 additional new patient-family dyads participated in the usability portion of the study, for which patients had a mean age of 3.18 years (SD ±2.98). Their indication for home ventilation was most commonly CLD from prematurity (60%) followed by impaired central control of breathing (30%) and mixed indication (10%, CLD and central control of breathing disorder). Participating caregivers had a mean age of 34.4 years old (SD ±4.25), all identified as female and included a diverse racial/ethnic family background (40% minority race/ethnicity, n=2 Black and n=2 Hispanic/Latinx) with a range of educational background (50% with less than college degree).

Qualitative strengths of the device's design from the perspective of the majority of parent users (n=9) were the small size of the device and its simplicity, "*I loved that it was compact. It's very bright. It's easy to use and that the fonts of the numbers [are] very large,*" (Parent 2) and "*I like that it's really easy to use, really easy to put together,*" (Parent 9). In particular, parents explained that these features were important for active child who may be sensitive to anything new placed on their tracheostomy, "*[The PEC] is small and compact, which is helpful and [he] didn't mind it, which is probably the biggest obstacle...He's a very active kid. So having big, bulky things that you have to make him sit and then manage him and a big bulky piece of machinery is not ideal....he already pulls off his vent circuit when he doesn't want it. So, something as small as the [PEC], if he didn't like it, we would never get a reading because he would just pull it off,*" (Parent 3) and "*I liked that it was really small and it's not heavy, so I don't think he really notices....,*" (Parent 4). Two children did need distraction techniques including dangling a toy or showing of a phone screen during the initial measurements to avoid the child grabbing at the device or vocalizing through the device, but measurements were able to be obtained once the child was calmed per the established protocol. While the study presented the goal of the PEC measurement for use in chronic weaning management, three parents identified the potential for its use during acute illness.

The main constructive feedback by 3 patient-parent dyads was that obtaining measurements during sleep could disrupt the child if they slept prone and/or lightly, for example, "*The only trouble we had was during nap. Only because he's a light sleeper. And when I tried to do it while he was sleeping, he wasn't having it. Just woke up in between it. I was able to put him back to sleep...It was a little process.*" (Parent 3)

Another parent explained trying to avoid waking the child by putting the PEC farther down the circuit during sleep to minimize disruption but worried the numbers were off, so readjusted it directly at the tracheostomy tube, explaining, “*So I did go directly to his trach and I was getting a better number ...[so] the challenging part is just because how he sleeps, he sleeps on his belly, so it was really hard for me to get it in because [the device] is pretty bulky.*” (Parent 7) However, in each case, the parents were able to obtain measurements.

Overall, the survey-based feedback from the parent participants was positive with all respondents reporting they either agreed or strongly agreed that they could imagine using the device for their child’s care and that it could help with their child’s care (note: one parent did not complete the survey questions). Once home, almost all parents endorsed the PEC was usable by answering that they “strongly disagreed” that the PEC was “*hard to use*”. One respondent (Parent 3) was neutral (chose option “neither agree/disagree”); notably that parent was one of the parents who reported challenges with measurement during sleep. Finally, all responding parents either agreed and or strongly agreed that it was *easy* to remember how to use the device once home.

Discussion

In this study, we found that a PEC device was a feasible, acceptable, and usable tool to measure EtCO₂ values in-clinic and at home in children with invasive HMV in a range of positions and activity levels, with some limitations during prone sleep. The PEC EtCO₂ values were on average more closely aligned with the in-clinic TCM device than the in-clinic EtCO₂ device, which ran about 4 mmHg higher. This finding is consistent with previous research which showed that the PEC device measurement was lower than the PvCO₂ measured in infants¹³ and lower than EtCO₂ measured in anesthesia machines

in adults,²⁷ which authors attributed to gas mixing and dead space at the tracheostomy tube.¹³ While this study only correlated the PEC with in-clinic models, sidestream EtCO₂ measurement is already known to correlate with measurement of partial pressure of arterial carbon dioxide (PaCO₂) and is used in hospitalized children for clinical trending.²⁸ Together, this suggests that the PEC may be reasonably safe and accurate option for spot checking EtCO₂ and trending while at home at home when a child with a tracheostomy tube is either connected or disconnected from the ventilator circuit. However, because EtCO₂ is only one datum relevant for evaluating ventilation management and because the PEC EtCO₂ values did not correlate perfectly with the in-clinic models, clinical decision-making regarding ventilation management should be done within the context of the patient to include their other vital signs and clinical appearance, as would be done in a clinic setting. Future research is needed to investigate whether routine longitudinal use of the PEC at home in addition to other remote data collection can provide improved clinical decision-making protocols than in current practice.

In fact, at this time, American Thoracic Society Clinical Practice guidelines only recommend children with HMV to be sent home with a pulse oximeter and other equipment to ensure monitoring for hypoxia,²⁹ primarily for detection of acute deterioration rather than use in chronic ventilatory management. With the expansion of telemedicine virtual visits since the start of the COVID-19 pandemic in 2020, increasingly more provider face-to-face care is provided remotely.^{30,31} However, patients may still travel to provider visits for routine evaluation of their HMV care, in part so that their providers can conduct an objective assessment of how well their HMV is supporting their growth and development and whether the child's positive pressure support can be

decreased. Traveling with such children is frequently difficult, given the need to travel with two caregivers to ensure safety as well as transporting all the necessary equipment, which increases the already high burden of care for families of children receiving HMV. Developing healthcare delivery strategies that can safely support care in the home may help reduce some of this health care travel burden and allow for more proactive management between in-office visits.

Notably, Liptzin et al found that weaning with close observation in small groups of children with invasive HMV was safe, but found that intermittent EtCO₂ data collection was not feasible about half of the time despite showing good correlation with blood testing.¹¹ Given the small size of the PEC device, we found a high rate of feasibility and usability in our test population, albeit small, especially while awake, which may provide a potential opportunity to expand this weaning model more broadly. However, future work is needed to evaluate the clinical utility and cost effectiveness of monitoring CO₂ to support the weaning process, including developing methods for longitudinal tracking of CO₂ in a manner that integrates with provider workflows.^{9, 32} This future research should investigate what data can be collected during what parts of a child's daily routine to best inform clinical decision-making and how to best integrate that information into existing health platforms and workflows.³²

While the purpose of this study was focused on the feasibility of CO₂ collection at home to inform chronic ventilatory management, parents shared their ideas about its potential use for assessment during an illness causing acute deterioration. For example, if a child has viral illness that is affecting their respiratory clearance, including a home CO₂ data point may provide potentially helpful data to providers to decide on next steps in

care. However, further work would ideally assess the PEC performance during illness to assess its safety and use in that context.

Limitations

Given this evaluation was done in the outpatient setting in which tracheostomy tube leaks are not routinely measured, we were not able to report on whether presence of a large leak impacted measurement correlation or agreement. Also, the Bland-Altman procedure assumes a linear relation between errors and measurements, which may not be the case in extreme measurements; however, we did collect data from a range of clinical values. Despite previous research correlating capnography with CO₂ levels, this study also did not directly compare portable capnography with gold standard blood CO₂ levels. Likewise, we did not assess for correlation between CO₂ readings with patient size or HMV indication, which could potentially affect CO₂ readings. We also did not repeat the comparison of the PEC with other modalities in the home setting as was done in the clinic setting.

We also note that parents who consented to participate may be more comfortable with technology, potentially introducing both selection bias and more positive feedback than may be seen in a broader population; nonetheless, all parents with children with HMV typically have baseline experience with equipment, given their children's condition.

Lastly, whether CO₂ readings at home will benefit decision making surrounding weaning HMV support was not assessed in this study and should be the focus of future work prior to any widespread adoption.

Conclusions

A PEC is a non-invasive option for measuring EtCO₂ in children with HMV both on and off the ventilator circuit, with high internal consistency with values that trend similarly to in-clinic models. Family caregivers found the device acceptable and feasible for use at home, especially when awake, with potential to facilitate management of chronic ventilation remotely and even clinical deterioration at home in children with tracheostomy.

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Figure 1: Portable end-tidal capnograph use attached via pediatric tracheostomy tube

1A. Ventilator tubing attached

1B. No ventilator attached



Figure 2a: Correlation between Portable End-tidal Carbon Dioxide Measurements with In-Clinic End Tidal Device Measurements

Graphs shows correlation of 0.85 (95% confidence interval (CI), 0.70 to 0.93; P<0.01)

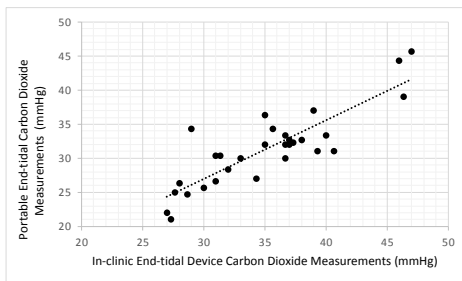


Figure 2b: Bland Altman Plot Comparing Portable End-tidal Carbon Dioxide Measurements with In-Clinic End Tidal Device Measurements

Dotted line at 0 indicates ideal (no difference between device measurements). The solid line indicates the mean of the differences, indicating the EMMA tends to be lower, on average, compared to the in-clinic end-tidal model. Thick dashed lines indicate ± 2 standard deviation.

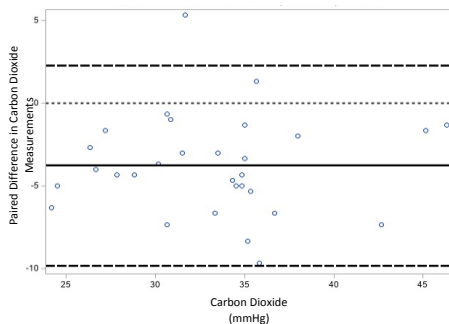


Figure 3a: Correlation between EMMA End-tidal Carbon Dioxide Measurements with Clinic Transcutaneous Device Measurements

Graphs shows correlation of 0.92 (95% confidence interval (CI), 0.83 to 0.96; $P < 0.01$).

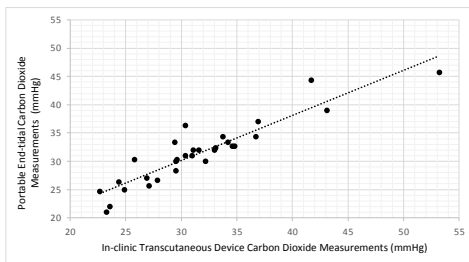


Figure 3b: Bland Altman Plot Comparing Portable End-tidal Carbon Dioxide Measurements with Clinic Transcutaneous Device Measurements

Dotted line at 0 indicates ideal (no difference between device measurements). The solid line indicates the mean of the differences, indicating the EMMA tends to be slightly lower, on average, compared to the in-clinic transcutaneous model. Thick dashed lines indicate ± 2 standard deviation.

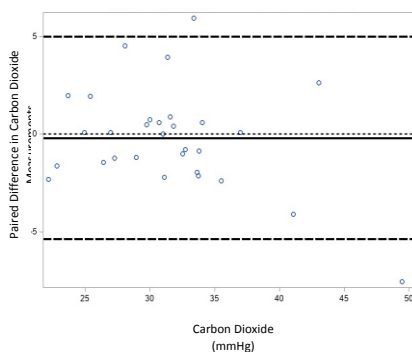


Table 1: Characteristics of Patients Participating in In-Clinic Measurements

Patient Characteristics	n (%)
Age in years, mean (SD)	4.9 (4.4)
Patient biological sex	
Male	17 (57)
Female	13 (43)
Patient Race Ethnicity	
Non-Hispanic White	14 (43)
Non-Hispanic Black	7 (23)
Hispanic/Latinx	7 (23)
Asian	3 (10)
Indication for Home Ventilation	
Chronic lung disease/Bronchopulmonary Dysplasia	15 (50)
Central control	8 (27)

Mixed indication	5 (16)
Neuromuscular	2 (7)
Anthropomorphic measurements, mean (SD)	
Patient weight in kg	19.5 (16.9)
Patient length in cm	91.0 (21.2)
Tracheostomy tube size (mm)	
3.5	4 (13)
4.0	11 (37)
4.5	8 (27)
5.0	4 (13)
6.0	1 (3)
Ventilator type	
LTV	25 (83)
Trilogy	5 (17)
Number of hours ventilated out of 24 on typical day, mean (SD)	19.6 (5.4)
Whether patient was using ventilator during measurement	
Yes, receiving positive pressure	21 (70)
No, not receiving positive pressure	9 (30)
Patient's activity level and position during measurement	
Awake calm, sitting	16 (53)
Asleep, laying down	4 (13)
Awake calm, laying	4 (13)
Awake active, sitting	3 (10)
Asleep, sitting	1 (3)
Awake active, laying down	1 (3)
Awake calm, laying down	1 (3)
Tracheostomy tube inflated during measurement	
Yes, inflated cuffed tube	16 (53)
No, not inflated or no cuff	14 (47)