

Testing an Oxygen Demand Delivery Device

Kyle M. Burk, Joseph A. Orr

Abstract— Introduction: Anesthesia care providers routinely deliver supplemental O₂ during monitored anesthesia care to prevent hemoglobin desaturation. The existing method of delivery, however, contributes to complications including respiratory depression and fire hazard. Patient variability also makes delivering O₂ difficult. We have developed a demand oxygen delivery system that only gives oxygen during early inspiration. We designed a volunteer study to evaluate patient monitoring and to compare continuous flow to demand delivery. We hypothesized that ceasing oxygen delivery during expiration will facilitate reliable capnography in non-intubated patients. We also hypothesized that delivering oxygen on demand leads to higher alveolar oxygen concentrations and higher hemoglobin saturation. **Methods:** We recruited thirty healthy volunteers. We asked volunteers to lie down in a hospital bed and fitted them with a nasal cannula and a pulse oximeter. Our prototype system delivered both constant and demand oxygen delivery, one at a time, of flows between 0 and 10 L/min. Each flow rate and mode combination was delivered for two minutes. At the end of each two-minute period, oxygen flow was turned off and the expired oxygen and carbon dioxide was sampled for three breaths. **Results:** When using demand delivery, the observed etCO₂ value was within ± 0.57 mm Hg for all flow rates. When using constant mode, the error increased as the supplemental O₂ flow rate increased. Statistical analysis showed no significant difference when monitoring etCO₂ using demand delivery. A statistically significant ($P < 0.05$) difference in etCO₂ measurement was observed for all rates when monitoring etCO₂ during constant flow. ETO₂ values were significantly higher ($P < 0.05$) during demand delivery than during continuous flow. Higher SpO₂ values were also observed during demand delivery. For flow rates of 1-4 L/min, less than 40% percent of constant flow oxygen values were needed to obtain equivalent ETO₂ concentrations when using demand oxygen delivery. **Discussion:** EtCO₂ can be monitored

accurately when supplemental O₂ delivery is interrupted during expiration. Demand delivery is useful for delivering O₂ while still ensuring accurate etCO₂ readings on exhalation. Higher ETO₂ concentrations and SpO₂ values can be achieved using demand oxygen delivery. These findings are consistent with prior evaluation of demand oxygen delivery systems used for long-term oxygen therapy. This study has shown that our intelligent oxygen flowmeter can obtain ETO₂ and SpO₂ values equivalent to or higher than continuous flow oxygen delivery while providing the benefits of demand oxygen delivery including reduced operating room fire hazard

Index Terms—Supplemental Oxygen Delivery, Capnography Accuracy, Oxygen Delivery Efficiency

I. INTRODUCTION

Anesthesia care providers routinely deliver supplemental oxygen during monitored anesthesia care to prevent hemoglobin desaturation. The existing method of delivery, however, contributes to complications. Respiratory depression occurs in $< 1\%$ of patients but may lead to brain damage and death.^{1,2} Supplemental oxygen delivered at constant high flow interferes with end-tidal carbon dioxide measurement by diluting exhaled carbon dioxide.^{3,4} Additionally, supplemental oxygen maintains high arterial oxygen levels even during minimal flow, thereby preventing pulse oximetry from notifying clinicians of respiratory depression.⁵ Since supplemental oxygen delivery compromises both carbon dioxide and pulse oxygen saturation monitoring methods, clinicians delivering supplemental oxygen lack a reliable means for detecting respiratory depression. Patient variability also makes delivering oxygen difficult. Maintaining sufficient levels of pulse oxygen saturation is challenging because the response of a given individual to particular oxygen flow rates is unpredictable.

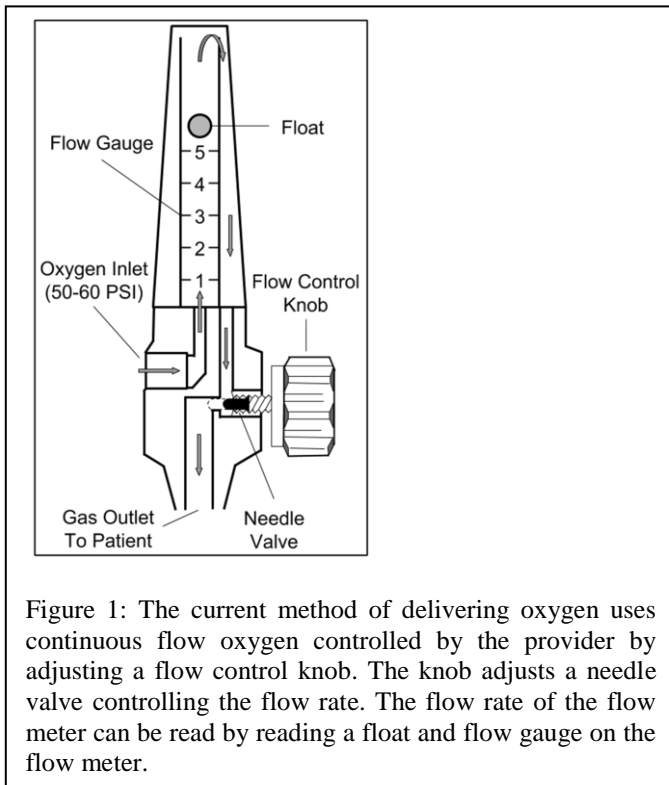
Traditionally, oxygen is delivered continuously via nasal cannula regardless of breath phase. An alternative method for delivering supplemental oxygen is demand oxygen delivery. Demand oxygen delivery gives a pulse of oxygen at the

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beginning of inspiration and stops oxygen flow during expiration. Fuhrman *et al.* compared the performance of continuous oxygen flow and demand oxygen delivery systems and found that demand oxygen delivery systems tend to deliver greater fraction of inspired oxygen⁶. However, some manufacturers maintain their numerical settings are equivalent to corresponding values of continuous flow while experimental data suggests settings are somewhat arbitrary and falsely imply equivalence to continuous flow.^{6,7,8}

Although demand oxygen delivery systems are widespread for home use, these systems are currently not used to deliver supplemental oxygen during sedation and monitored anesthesia care. Existing demand delivery devices have not been adapted for use during sedation and monitored anesthesia care. These devices are meant for unhealthy lungs and increase oxygen delivery as the patient increases their effort. They are not suitable for procedural sedation where the system must deliver adequate oxygen when the patient's respiratory effort is decreased.

Current in-hospital oxygen delivery systems involve a needle valve and floating ball type flow meter (Fig. 1). The oxygen flow rate is set by adjusting a flow control knob and reading a flow gauge. This method of setting flow rate may lead to

a discrepancy between the prescribed and actual flow rate.⁹

We have developed a demand oxygen delivery system that only gives oxygen during early inspiration.¹⁰ The prototype determines breath rate and inspiratory effort by measuring intranasal pressure through a cannula port (Figure 2). The system uses the measured breath rate to adjust the volume of oxygen delivered during each inspiration. Using this method, the amount of flow given by the system varies according to the patient's respiration rate so that as their breath rate slows, the amount of oxygen delivered per breath is increased. This is an important aspect of the proposed system as the drugs given during monitored anesthesia care depress breathing. Increasing the amount of oxygen delivered when the patient's breath rate slows ensures that the volume of inhaled oxygen remains constant regardless of breath rate. The system detects patient breath rate and automatically delivers continuous oxygen and notifies the clinician when the patient stops breathing.

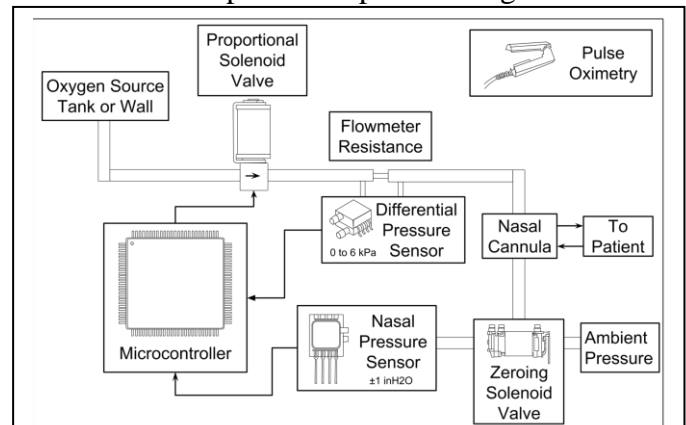


Figure 2: Schematic diagram of the oxygen delivery system. The system determines breath rate and inspiratory effort by measuring intranasal pressure through a cannula port. A digital pressure sensor continuously samples nasal pressure. In order to compensate for sensor drift, the nasal pressure sensor measures ambient pressure using a 3-way pneumatic solenoid valve. A microcontroller reads the nasal pressure measurement and drives the proportional solenoid valve. A differential pressure type flow sensor measures flow rate through the valve. The microcontroller's A/D converter reads the differential pressure sensors analog output and calculates flow based on a calibration. A commercial pulse oximeter measures pulse oxygen saturation.

Capnography accuracy and oxygen delivery efficiency highlight a gap between clinical needs and the current care delivered. This gap may be filled using an alternative approach to supplemental

oxygen delivery. Therefore, we designed a volunteer study to evaluate patient monitoring and to compare continuous flow to demand delivery. In our study we compared the accuracy of carbon dioxide monitoring using the conventional constant mode and our prototype’s demand mode. We also determined the amount of demand oxygen necessary to provide equivalent end-tidal oxygen levels as continuous flow delivery in volunteers.

For the first portion of this study, we compared continuous flow oxygen to demand delivery. We hypothesized that delivering oxygen on demand leads to higher alveolar oxygen concentrations and higher hemoglobin saturation.

For the second part of this study, we evaluated the accuracy of end-tidal carbon dioxide measurements while delivering oxygen on demand. We hypothesized that ceasing oxygen delivery during expiration will facilitate reliable capnography in non-intubated patients. Continuous delivery inhibits respiratory monitoring by preventing carbon dioxide measurements from reaching breath detection thresholds.

II. METHODS

A. Volunteer Study

After receiving University of Utah Institutional Review Board approval, we recruited thirty healthy volunteers (16 Male, 14 Female, average age = 34). We asked volunteers to lie down in a hospital bed and we fitted them with a nasal cannula (Teleflex Medical Softech® Bi-Flo) and a pulse oximeter (Masimo LNCS DCI-P). We modified the cannula with ports for oxygen delivery and sampling carbon dioxide and intranasal pressure. The cannula sensing port was connected to the system’s pressure sensor and to an oxygen and carbon dioxide gas analyzer (CapnoMAC, Datex, Helsinki, Finland). During the study, our prototype system delivered both constant and demand oxygen delivery, one at a time, of flows between 0 and 10 L/min. Each flow rate and mode combination was delivered for two minutes. At the end of each two-minute period, oxygen flow was turned off and the expired oxygen and carbon dioxide was sampled for three breaths (Figure 3). Oxygen and carbon dioxide waveforms were collected from the gas analyzer at 100 Hz. Waveform analysis was performed using a custom computer program.

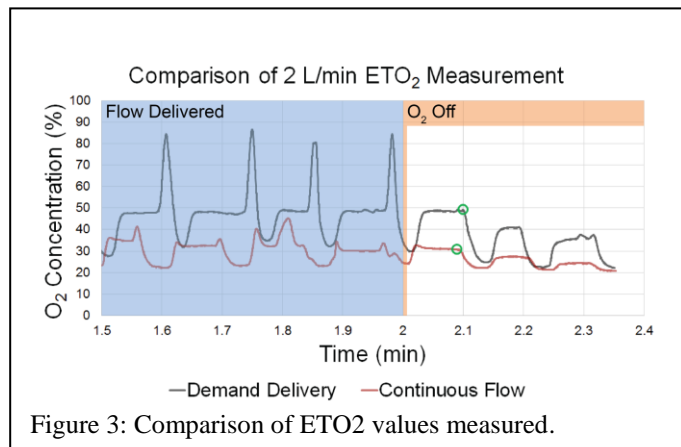


Figure 3: Comparison of ETO2 values measured.

B. Capnography Accuracy

A baseline end-tidal carbon dioxide was collected with no oxygen flowing at the beginning of the testing period. A simple threshold algorithm was used for breath cycle analysis, where start of expiration occurred when carbon dioxide rose above 20 mm Hg and start of inspiration occurred when carbon dioxide fell below 5 mm Hg. end-tidal carbon dioxide was considered as the maximum carbon dioxide during a breath cycle. Although there were no actual instances of apnea during the study, “false apnea” based solely on capnometry could occur if the expired gas became too diluted. For purposes of our analysis, end-tidal carbon dioxide was set to 0 mmHg after 10 or more seconds of false apnea. The average end-tidal carbon dioxide value for each flow and mode combination was calculated and compared to the baseline value. A t-test was used to determine whether there was a statistically significant difference between end-tidal carbon dioxide measured with oxygen flow and the baseline end-tidal carbon dioxide.

C. Oxygen Delivery Efficiency

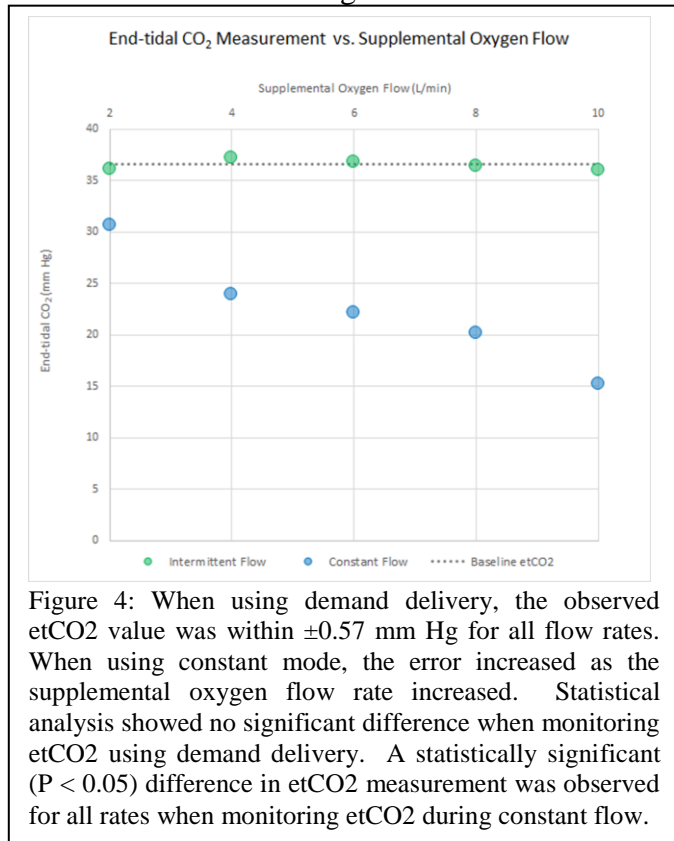
End-tidal oxygen values will be collected at the end of the two minute period by shutting of oxygen flow. In order to avoid affecting oxygen concentrations, we did not sample oxygen during oxygen delivery. Because of this, we had to estimate the end-tidal oxygen prior to turning off the oxygen. We estimated the end-tidal oxygen prior to turning off the oxygen using a backward linear extrapolation of the three expired end-tidal oxygen values. The time that end of expiration occurred was found by referencing the time that expired carbon dioxide reached its peak level. A t-test was used to

determine whether there was a statistically significant difference between oxygen levels achieved with demand delivery and oxygen levels achieved with continuous flow.

III. RESULTS

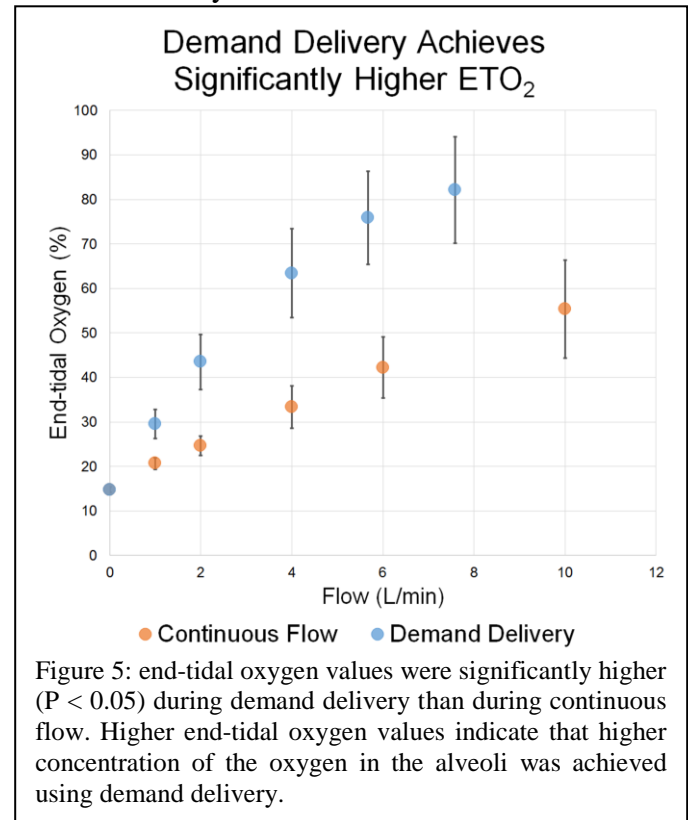
A. Capnography Accuracy

Figure 4 shows the end-tidal carbon dioxide measurement values for both modes at all flow rates. When using demand delivery, the observed end-tidal carbon dioxide value was within ± 0.57 mm Hg for all flow rates. When using constant mode, the error increased as the supplemental oxygen flow rate increased. The end-tidal carbon dioxide measurement was 5.97 mm Hg below baseline at 2 L/min constant flow. The largest error occurred when delivering constant flow at 10 L/min where the end-tidal carbon dioxide measurement was 21.45 mm Hg below baseline. Statistical analysis showed no significant difference when monitoring end-tidal carbon dioxide using demand delivery. A statistically significant ($P < 0.05$) difference in end-tidal carbon dioxide measurement was observed for all rates when monitoring end-tidal carbon dioxide during constant flow.



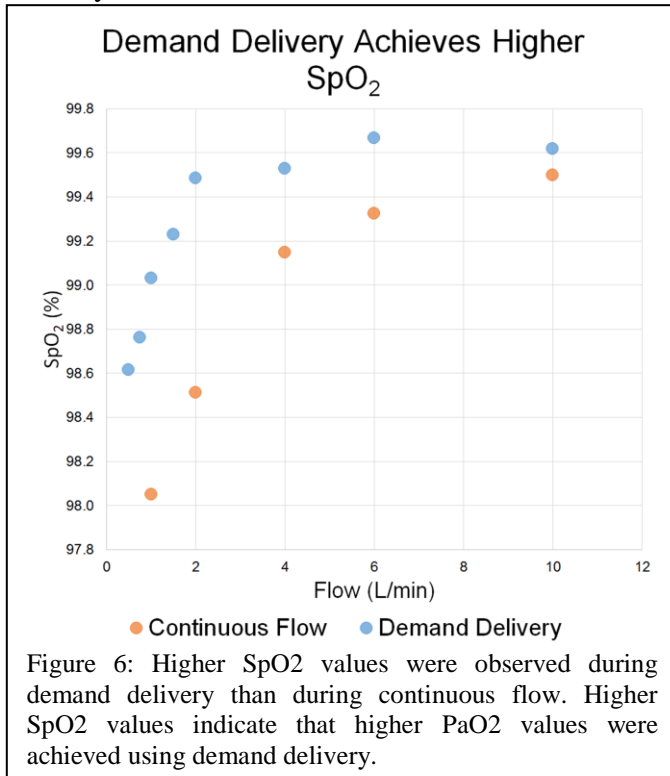
B. Oxygen Delivery Efficiency

End-tidal oxygen values were significantly higher ($P < 0.05$) during demand delivery than during continuous flow (Figure 5). Higher end-tidal oxygen values indicate that higher concentration of the oxygen in the alveoli was achieved using demand delivery.



Higher pulse oxygen saturation values were also observed during demand delivery, indicating that higher partial pressure of arterial oxygen values were achieved (Figure 6). For oxygen flows of 1-4 L/min, 100% of the oxygen was delivered during demand delivery. For higher flows during demand delivery, the system was not able to deliver the set oxygen flow because inspiration was either too shallow or too short as indicated by the measured nasal pressure. On average, 95% of oxygen was delivered during 6 L/min set flow and 76% of oxygen was delivered during 10 L/min set flow. Even though demand delivery gave less oxygen when the flow rate was 6 and 10 L/min, the end-tidal oxygen concentrations and pulse oxygen

saturation values were still higher than continuous flow at the same rates. For flow rates of 1-4 L/min, less than 40% percent of constant flow oxygen values were needed to obtain equivalent end-tidal oxygen concentrations when using demand oxygen delivery.



IV. DISCUSSION

A. Capnography Accuracy

End-tidal carbon dioxide can be monitored accurately when supplemental oxygen delivery is interrupted during expiration. Demand delivery is useful for delivering oxygen while still ensuring accurate end-tidal carbon dioxide readings on exhalation. Our prototype may enable clinicians to use capnometry more accurately during supplemental oxygen delivery while at the same time providing a secondary method for detecting respiratory depression by monitoring nasal pressure.

B. Oxygen Delivery Efficiency

Higher end-tidal oxygen concentrations and pulse oxygen saturation values can be achieved using demand oxygen delivery. These findings are consistent with prior evaluation of demand oxygen delivery systems used for long-term oxygen therapy. Even though the prototype system delivers

oxygen on demand, end-tidal oxygen concentrations are higher since all of the oxygen delivered is inhaled. This study has shown that our intelligent oxygen flowmeter can obtain end-tidal oxygen and pulse oxygen saturation values equivalent to or higher than continuous flow oxygen delivery while providing the benefits of demand oxygen delivery including reduced operating room fire hazard.¹¹

Our demand delivery method may have broad impact by improving patient monitoring and increasing oxygen delivery efficiency. Our demand delivery method could avoid diluting capnography by ceasing oxygen delivery during exhalation. Facilitating reliable capnography during supplemental oxygen delivery would allow for detecting hypercarbia in patients. Our demand delivery method has also allowed a means for comparing continuous flow oxygen to demand delivery. This comparison has provided data which could deliver the appropriate amounts of oxygen when using demand mode and remove the need for titrating oxygen levels to specific patients.

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