Development of an Oxygen Conserving Device

Kyle M. Burk, Joseph A. Orr

***Abstract*— <u>Introduction:</u> Supplemental oxygen is often given to awake, sedated patients in order to decrease the frequency and depth of oxygen desaturation caused by periods of respiratory depression and airway obstruction. The Anesthesia Patient Safety Foundation has expressed that postoperative opioid-induced respiratory depression remains a serious patient safety risk associated with significant adverse events. Operating room fires are another preventable adverse event associated with constant flow oxygen with approximately 100 operating room fires occurring per year. Patient discomfort is another concern associated with conventional supplemental oxygen delivery. We have developed an intelligent supplemental oxygen flowmeter that only gives oxygen at the start of inspiration and at low flows for a brief period during the expiratory pause. The prototype determines respiration rate (RR) and inspiratory effort by measuring intranasal pressure through a cannula port. In order to compare our device to conventional oxygen delivery, we designed a study comparing fire safety and patient comfort between conventional constant flow and intermittent pulsed flow. <u>Methods:</u> *Patient Comfort:* Thirty healthy volunteers were fitted with a nasal cannula while seated before a laptop computer. A semi-automated system administered nasal oxygen through the cannula at flow rates varying from 0 to 10 liters / min in increments of 2. Comfort levels were collected and managed using REDCap electronic data capture tools hosted at the University of Utah. After each condition, volunteers were also asked whether they experienced any difficulty breathing out through their nose. *Fire Safety:* We used a 3-D printed model of the human airways placed under simulated surgical drapes to compare both oxygen delivery modes. Oxygen was delivered via nasal cannula while the model breathed spontaneously at a tidal volume of 500 mL and respiratory rates of 4, 8 and 12 breaths/min. Supplemental oxygen was given at flow rates of 2 and 4 L/min using both conventional (constant flow) and controlled (pulsed inspired) mode. Oxygen concentrations were measured at 16 different locations on and around the face under the drape for all settings. <u>Results:</u> *Patient Comfort:* The average perceived discomfort was similar at 2 L/min. At flow rates of 4 l/min and above, intermittent inspiratory-only flow the average discomfort was significantly less (P = 0.05). *Fire Safety:* Across all settings and flow rates, the average oxygen concentration under the drapes using pulsed flow was 38% lower than when using continuous flow oxygen. Pulsed oxygen resulted in 88% higher average oxygen concentration in the lung. <u>Discussion:</u> *Patient Comfort:* At low flow rates, there is no difference between the perceived discomfort of the two modes. When supplemental oxygen flow is constant, discomfort increases with increasing flow rates. Using inspiratory only oxygen delivery, it may be possible to "pre-oxygenate" patients prior to administering sedatives and opioids during procedural sedation. *Fire Safety:* Using intelligent control of oxygen flow allows for a reduction in oxygen waste and hazard while increasing the amount of oxygen inhaled by the patient. Intelligent pulsed oxygen delivery may keep oxygen levels below the 26% threshold for significant fire hazard.**

***Index Terms*—Supplemental Oxygen Delivery, Operation Room Fire Hazard, Patient Comfort, Oxygen Conservation**

I. INTRODUCTION

Supplemental oxygen is often given to awake, sedated patients in order to decrease the frequency and depth of oxygen desaturation caused by periods of respiratory depression and airway obstruction. Respiratory depression, when the patient's breathing is inadequate to provide adequate oxygen to the body, and airway obstruction after surgery are often induced by opioids administered during surgery. The Anesthesia Patient Safety Foundation has expressed that postoperative opioid-induced respiratory depression remains a serious patient safety risk associated with significant adverse events [1]. In a 2004 meta-analysis of 165 articles on postoperative pain management, Cashman and Dolin found the incidence of respiratory depression to range from 0.1 to 37% depending on the analgesic technique

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and the method of detecting respiratory depression [2]. In a 2015 analysis of the Anesthesia Closed Claims Project database, Lee et al. found that more than half of the patients who experienced respiratory depression died and another 22% had severe brain damage. They noted that 97% of these deaths and injuries were judged as preventable with better monitoring [3]. Besides limiting patient monitoring, supplemental oxygen delivery introduces other risks during patient care.

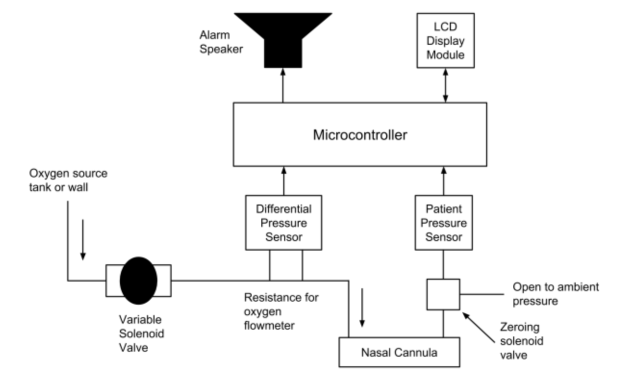

Figure 1: Schematic diagram of the prototype intelligent oxygen flowmeter. Nasal pressure is sampled from the patient via nasal cannula. The breath phase and respiratory rate are determined from the nasal pressure signal. Oxygen delivery is turned off during active exhalation and turned on during early inspiration and pause phase. When the respiratory rate slows, algorithms automatically increase the amount of oxygen given per breath. Oxygen is delivered using a variable solenoid valve connected to an oxygen source. The flow rate is measured using a differential flow sensor. An LCD display and alarm provide human-machine interaction for the operator.

Operating room fires are another preventable adverse event associated with constant flow oxygen [4]. Approximately 100 operating room fires occur per year and result in significant patient morbidity and mortality [5]. Mehta et al. reported that 1.9% of all operating room adverse events that resulted in closed insurance claims were caused by fires with electrocautery as the ignition source for 90% of these fires. Most (85%) of electrocautery fires occurred during head, neck, or upper chest procedures (high-fire-risk procedures). Delivered O2 served as the oxidizer in 95% of electrocautery-induced OR fires and 84% of these occurred when oxygen was given with an open delivery system (nasal cannula or mask) [6].

A significant hazard for fire exists with a 26% or greater oxygen concentration [7]. Supplemental oxygen delivery creates a cloud around the patient which then decreases the ignition time for commonly used surgical items [8]. Using standard oxygen flowmeters, O2 flows continuously into the patient's nostrils even during exhalation resulting in wasted O2 that flows between the surgical drapes and into the room greatly increasing the amount of fire promoting oxidizer in the operating room.

When sedation is minimal, patients may complain of discomfort caused by high flow oxygen delivered via nasal cannula into the nares. Discomfort may be more severe when the patients are monitored using cannulas designed to sample CO_2 since the cross-sectional area of the oxygen delivery port is smaller causing oxygen to jet into the nostril(s).

Fire risk during surgery and patient discomfort highlight a gap between clinical needs and the current care delivered. This gap may be filled using an alternative approach to supplemental oxygen delivery.

We have developed an intelligent supplemental oxygen flowmeter that only gives oxygen at the start of inspiration and at low flows for a brief period during the expiratory pause. The amount of flow given by the system varies according to the respiration rate so that as the respiration rate slows, the amount of inhaled oxygen is increased so that the volume of inhaled O_2 remains constant regardless of breath rate.

The prototype determines respiration rate (RR) and inspiratory effort by measuring intranasal pressure through a cannula port. The system uses measured RR to adjust the O2 volume delivered during each inspiration.

The intermittent delivery method may have broad impact by improving patient safety, reducing costs, and increasing patient comfort and compliance. With the goal to fill in knowledge gaps for fire safety and patient comfort, we designed a study comparing fire safety and patient comfort between conventional constant flow and intermittent pulsed flow.

For the first part of this study, we evaluated how well high flow nasal oxygen is tolerated if it is only given during inspiration in volunteers. We hypothesized that the majority of discomfort associated with oxygen delivery is experienced when the patient is breathing out against the oxygen flow. During the expiratory phase of respiration, as the patient is breathing out, the supplemental oxygen flowing into the nares raises intra-nasal pressure increasing discomfort. Furthermore, high flow during the expiratory pause adds to the perceived discomfort by drying the nasal mucosa.

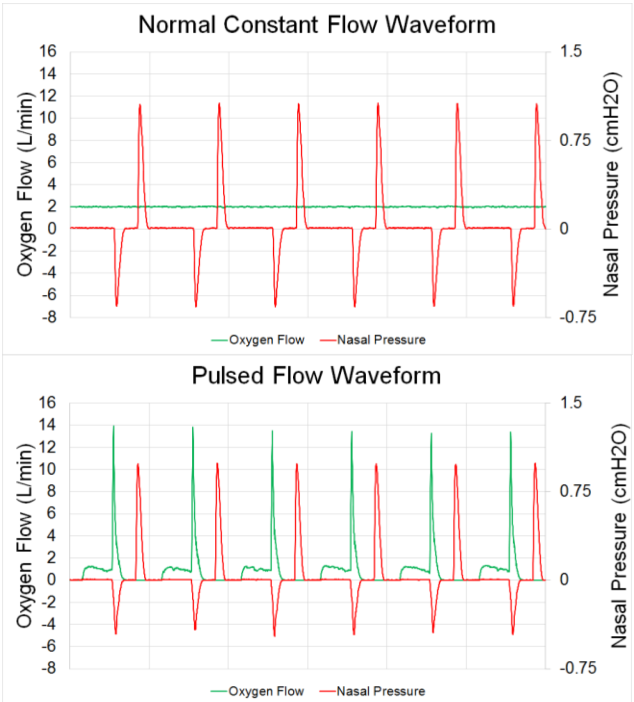

Figure 2: Sample pressure and flow waveforms for constant (top) and pulsed (bottom) delivery methods. The pulsed method reduces the volume of open source O2 delivered by carefully limiting O2 flow to periods during the early phase of inhalation, stopping O2 flow completely during expiration and limiting the rate and duration of oxygen flow during the pause phase of breathing. In our tests, the novel system achieves superior oxygen delivery while using 60% less oxygen thereby reducing the amount of possible oxidizer by 60% and as much as 90% as respiration rate decreases.

For the second portion of this study, we evaluated the difference in fire risk between using conventional and intermittent oxygen delivery. We hypothesized that delivering oxygen intermittently leads to lower surface concentrations of oxygen on the skin and thus lower fire hazard.

II. METHODS

A. *Patient Comfort*

Thirty healthy volunteers (21 Male, 9 female, average age = 34.4) were fitted with a nasal cannula (Softech Bi-Flo Cannula, Teleflex, Research Triangle Park, NC) while seated before a laptop computer. A semi-automated system administered nasal oxygen through the cannula at various flow rates using either continuous flow or pulsed inspiratory flow. The flow rates varied from 0 to 10 liters / min in increments of 2. The sequence of flow rate and mode pairings was randomly chosen for all patients.

Comfort levels were collected and managed using REDCap electronic data capture tools hosted at the University of Utah [9]. Volunteers were asked to rate the comfort level of the cannula with no oxygen flowing. Then, after breathing under each condition, the volunteers entered their level of discomfort into the survey using a slider / visual analog scale ranging from no discomfort to painful (0 being no discomfort and 100 being painful). After each condition, volunteers were also asked whether they experienced any difficulty breathing out through their nose. Statistical analysis using t-tests (SISA, Quantitative Skills, Netherlands) was performed on the comfort ratings to compare comfort between both modes at the same flow. A p-value less than 0.05 was considered statistically significant.

B. *Fire Hazard*

We used a 3-D printed model of the human airways placed under simulated surgical drapes (Medium Drape 112 - 76" X 44", Kimberly-Clark, Irving, TX) to compare both oxygen delivery modes. Oxygen was delivered via nasal cannula (Softech Bi-Flo Cannula, Teleflex, Research Triangle Park, NC) while the model breathed spontaneously at a tidal volume of 500 mL and respiratory rates of 4, 8 and 12 breaths/min. Supplemental oxygen was given at flow rates of 2 and 4 L/min using both conventional (constant flow) and controlled (pulsed inspired) mode. Oxygen concentrations were measured at 16 different locations on and around the face under the drape for all settings. After 2 minutes of equilibration during which no oxygen was sampled, each measurement was taken using a respiratory gas monitor (Capnomac Ultima, Datex, Helsinki, Finland). The oxygen concentration was sampled for 1 minute then the average and max of the oxygen concentrations during that 1 minute period were recorded. The system was calibrated to room air and 100% oxygen before each test period.

III. Results

A. *Patient Comfort*

Figure 3 shows the average relative discomfort for each of the tested flow rates for both conventional (constant flow) and intermittent (inspiratory only) oxygen delivery modes. The average perceived discomfort was similar at 2 L/min. At flow rates of 4 l/min and above, intermittent inspiratory-only flow the average discomfort was significantly less ($P = 0.05$).

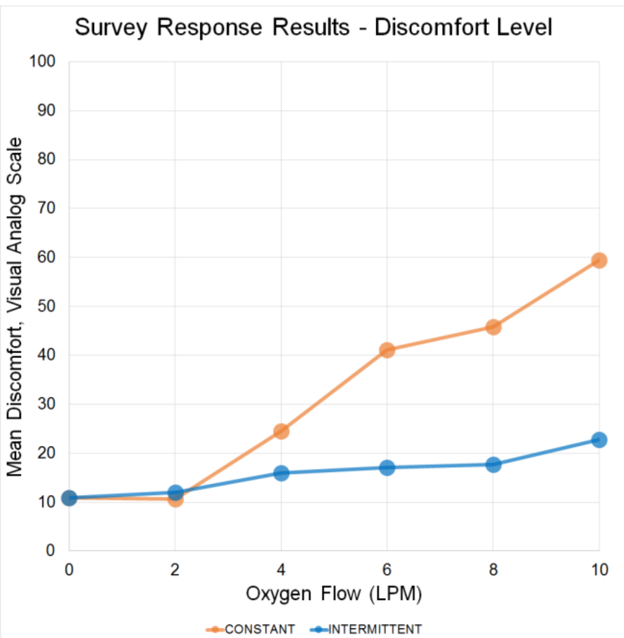

Figure 3: Comfort level reported by volunteers by an online survey using a visual analog scale ranging from 0 to 100 where 0 indicated no discomfort and 100 indicated pain. Flows ranging from 0 to 10 were rated. The average perceived discomfort was similar at baseline and 2 L/min. At flow rates of 4 L/min and above, the average discomfort during intermittent inspiratory-only flow was significantly less ($P = 0.05$) than constant delivery at the equivalent flow. The most discomfort was experienced during 10 L/min constant flow and the average rating was 59. Baseline comfort (no oxygen flow rating) was rated as 11 on average.

Figure 4 shows the difficulty exhaling reported by volunteers for both modes. During intermittent delivery, only 1 out of 30 volunteers experienced difficulty exhaling for all flows. During constant flow delivery, the percent of volunteers experiencing difficulty exhaling increased as flow increased. At 2 L/min, only 1 out of the 30 volunteers experienced difficulty exhaling during constant delivery. At 10 L/min, 20 out of 30 (67%) volunteers experienced difficulty exhaling during constant delivery.

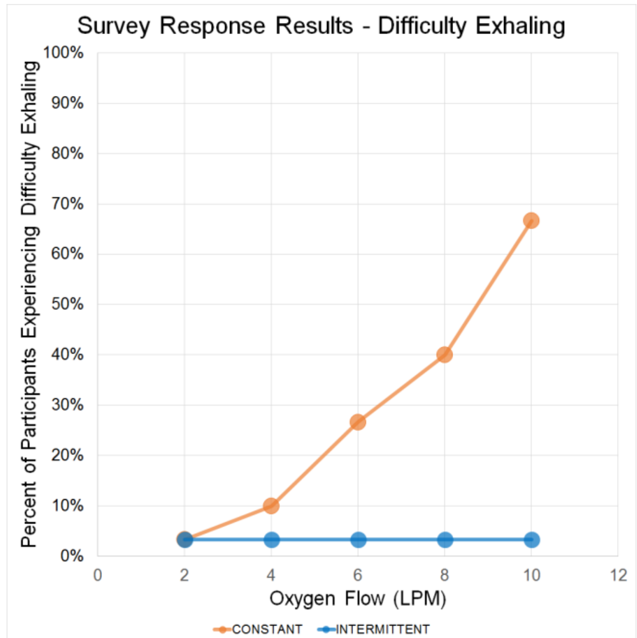

Figure 4: Difficulty exhaling reported by volunteers by an online survey. Volunteers were asked "are you experiencing any difficulty breathing OUT through your nose?" During intermittent delivery, only 1 out of 30 volunteers experienced difficulty exhaling for all flows. During constant flow delivery, the percent of volunteers experiencing difficulty exhaling increased as flow increased. At 2 L/min, only 1 out of the 30 volunteers experienced difficulty exhaling during constant delivery. At 10 L/min, 20 out of 30 (67%) volunteers experienced difficulty exhaling during constant delivery.

B. *Fire Hazard*

Across all settings and flow rates, the average oxygen concentration under the drapes using pulsed flow was 38% lower than when using continuous flow oxygen. The average oxygen concentration under the drapes using the pulsed oxygen was 25.0% while it was 40.6% using constant flow. The maximum observed oxygen concentration was

83.27% when using constant flow of 2 l/min and was 35.36% using pulsed flow. We measured the oxygen concentration in the lung simulator to assess oxygenation. Pulsed oxygen resulted in 88% higher average oxygen concentration in the lung. Figure 5 shows a map of oxygen concentration under surgical drapes on a 3-D printed model of the face at 4 breaths per minute and 2 L/min oxygen flow. The bottom plot corresponds to pulsed flow delivery and the top plot corresponds to conventional (constant) flow. Note that oxygen delivery to the simulated lung was higher using pulsed flow for every simulated setting.

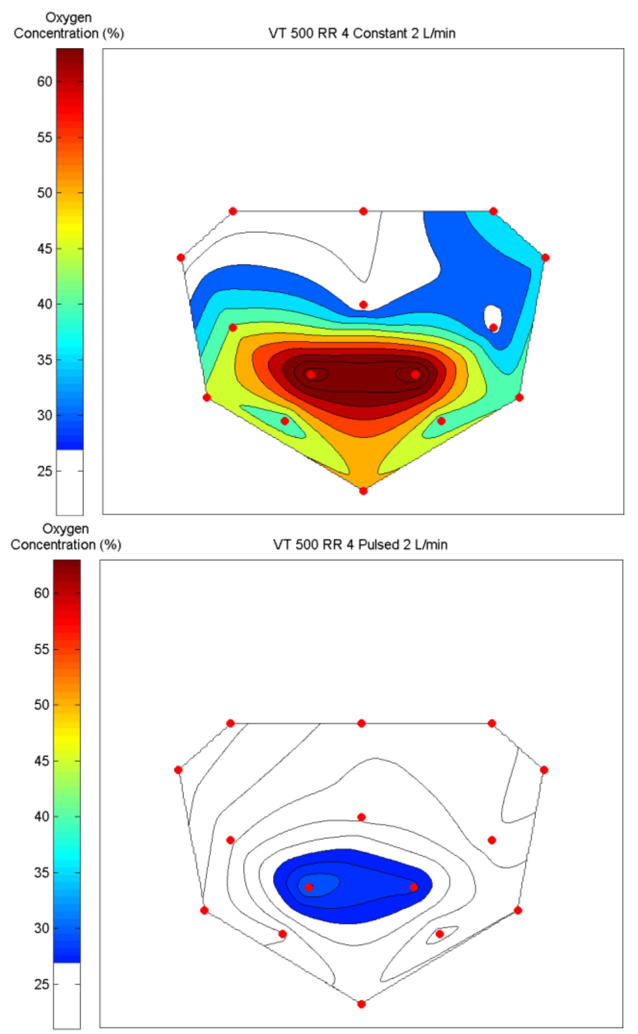

Figure 5: Map of oxygen concentration on the face under surgical drapes during simulated spontaneous breathing. Comparison of oxygen concentrations using constant (top) and pulsed (bottom) methods to deliver 2 L/min oxygen to a mock patient with VT 500, RR 4.

IV. Discussion

A. Patient Comfort

At low flow rates, there is no difference between the perceived discomfort of the two modes. When supplemental oxygen flow is constant, discomfort increases with increasing flow rates. When oxygen flow is turned off during exhalation, the average level of perceived discomfort does not change significantly regardless of the flow rate. Using a time controlled oxygen delivery scheme creates the possibility of giving high flows of oxygen without additional patient discomfort. Using inspiratory only oxygen delivery, it may be possible to “pre-oxygenate” patients prior to administering sedatives and opioids during procedural sedation. Further, using an inspiration only delivery method for supplemental oxygen relieves the patient of difficulty exhaling. Allowing the patient to exhale with greater ease could be one reason patient comfort increases during intermittent delivery. Another reason could be that during expiration the patient is able to hydrate the nasal cavity with humidified air from the lungs.

Patient comfort did decrease slightly with increasing flow during intermittent mode, although at a much lower rate than during constant flow. This could be due to the fact that with greater flows more oxygen was pulsed during each inhalation. Although comfort did decrease slightly with increasing oxygen flow, the decrease was significantly less than the decrease observed using constant flow as signified by the statistical difference observed at flows of 4 liters / minute and greater.

B. Fire Hazard

Using intelligent control of oxygen flow allows for a reduction in oxygen waste and hazard while increasing the amount of oxygen inhaled by the patient. Intelligent pulsed oxygen delivery may keep oxygen levels below the 26% threshold for significant fire hazard. Intermittently delivering supplemental oxygen could potentially allow for oxygen delivery during high fire risk procedures (head, neck, or upper chest) without increasing fire hazard.

Intermittent delivery of supplemental oxygen reduces the amount of oxygen clouding around the patient. Oxygen is delivered during inspiration and is instantly inhaled into the patient's lungs. The oxygen is then shut off during expiration where during conventional constant flow the oxygen cloud is created.

An intermittent oxygen delivery device has been shown to increase patient comfort during oxygen delivery and reduce fire hazard when using open oxygen delivery systems. We expect to conduct further research to determine additional benefits from implementing this system for supplemental oxygen delivery.

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