A Challenging Patient: approaches to controlling FiO2 during highly unstable oxygen saturation.

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Following the critical phase of their care, some infants experience frequent episodes of significant oxygen desaturation. Maintaining good control of SpO2, while at the same time weaning oxygen, can be most challenging. We present this case study of such an infant. We include information on the relative effectiveness of a new closed loop FiO2 control system (Avea-CLiO2, CareFusion Yorba Linda CA) and two manual FiO2 titration approaches. While this infant was unusually challenging, we have been using CLiO2 routinely for about 1 year and have found it to be very effective in a broad range of patients. Based on this general clinical experience and on our controlled trial,1 we have found Avea-CLiO2 to likely be more effective than the best manual care and to result in a significant reduction in nursing labor.

This female was born at another hospital at an estimated gestational age of 27 weeks, weighing 800 grams. Having experienced intrauterine asphyxia, she required cardiopulmonary resuscitation in the delivery room. Subsequently after not responding to NCPAP, she was intubated and transferred to our center at 4 hours of age. Upon arrival she was stabilized with surfactant but required an FiO2 of 80%. Her primary diagnosis was RDS with grade II IVH and hypothermic syndrome. The early course of treatment was complicated with a FDA and hemodynamic instability, both treated medically. By the 10th day of SIMV (20/5 rate 50) her FiO2 had been weaned to below 30%, but she was experiencing frequent severe episodic desaturation spells (9/hour < 80% SpO2). For this reason she was placed on the Avea-CLiO2 ventilator with automated FiO2. Two days later she was enrolled in a study1 to compare automated CLiO2 control to two protocol-driven FiO2 adjustment strategies implemented by a dedicated operator to CLiO2 for approximately 7.5 hours. As can be seen in Figure 1 during CLiO2 use, SpO2 control was much more effective than during the periods of manual adjustment. The frequency and severity of episodes of severe hyper and hypoxemia were markedly reduced with CLiO2. Following this study period, she was placed back under CLiO2 FiO2 control, and the course over the next 14 hours is documented in Figure 2. During this period her SpO2 remained very unstable but FiO2 was, nevertheless, automatically weaned. She remained on Avea-CLiO2 until she was extubated 9 days later. She was then placed on SiPAP and weaned to NCPAP over the next 11 days. She was discharged home without the need for supplemental oxygen, mild BPD and grade II ROP.

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**CLiO2 Theory of Operation**

CLiO2 utilizes a sophisticated patented control system. While monitoring SpO2 virtually continuously, CLiO2 compares the SpO2 to the clinician selected target range. Every 1 second CLiO2 considers a change to the FiO2. If the SpO2 is outside the target range, the FiO2 change is based not only on the duration and magnitude/depth of the episode but also on the trajectory of the SpO2.

CLiO2 considers a baseline FiO2 level to facilitate returning to the target range as quickly as possible and minimizing overshoot beyond the target range. The baseline FiO2 is initially set by the clinician and updated automatically based on the infant’s course. The time constant of the update is based on the infant’s SpO2 stability. That is, the more stable the more quickly the baseline is changed.

In addition, when the SpO2 is within the upper half of the desired target range, the FiO2 is slowly weaned down to bring it to the mid-point of the desired range. Furthermore, even when in the target range, CLiO2 identifies rapid changes in SpO2 and responds in anticipation of a significant excursion.

Finally, in addition to traditional SpO2 alarms, CLiO2 also offers two other safety features. First, should CLiO2 need to increase FiO2 significantly to maintain SpO2 in the target range, an alert is provided to the clinician. Second, should the oximeter signal drop out, or be of poor quality, CLiO2 returns the FiO2 to the clinician set backup FiO2 or the most recent FiO2, whichever is higher.

CLiO2 has been shown in two controlled trials, when compared to routine care, to markedly increase time in intended SpO2 target range, to reduce time in severe hyperoxemia without increasing time in severe hypoxemia and to reduce the level of inspired oxygen.

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**Figure 2. Subsequent CLiO2 Control – 14 hours.** The chart shows the FiO2 (red) and SpO2 (blue) based on 1-minute rolling averages of 5-second data points. Each tick on the time axis represents 45 minutes. In this chart CLiO2’s response to acute hyper and hypoxemia episodes remains apparent, but the longer period of time also affords the opportunity to see CLiO2’s response to less acute trends in SpO2. In the early part of this period, at a time when the SpO2 was relatively stable but drifted above the control range, the FiO2 was reduced to 21%. Immediately following this, the FiO2 was increased when the SpO2 deteriorated. Over this 14-hour period of time, however, CLiO2 automatically reduced the FiO2 from a baseline of 25% to 21%.

**References**