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ORIGINAL CLINICAL RESEARCH REPORT

Oxygen Reserve Index: Utility as an Early Warning for Desaturation in High-Risk Surgical Patients

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BACKGROUND: Perioperative pulse oximetry hemoglobin saturation (Spo_2) measurement is associated with fewer desaturation and hypoxia episodes. However, the sigmoidal nature of oxygen–hemoglobin dissociation limits the accuracy of estimation of the partial pressure of oxygen (Pao_2) >80 mm Hg and correspondingly limits the ability to identify when Pao_2 >80 mm Hg but falling. We hypothesized that a proxy measurement for oxygen saturation (Oxygen Reserve Index [ORI]) derived from multiwavelength pulse oximetry may allow additional warning time before critical desaturation or hypoxia. To test our hypothesis, we used a Masimo multiwavelength pulse oximeter to compare ORI and Spo_2 warning times during apnea in high-risk surgical patients undergoing cardiac surgery.

METHODS: This institutional review board–approved prospective study (NCT03021473) enrolled American Society of Anesthesiologists physical status III or IV patients scheduled for elective surgery with planned preinduction arterial catheter placement. In addition to standard monitors, an ORI sensor was placed and patients were monitored with a pulse oximeter displaying the ORI, a nondimensional parameter that ranges from 0 to 1. Patients were then preoxygenated until ORI plateaued. Following induction of anesthesia, mask ventilation with 100% oxygen was performed until neuromuscular blockade was established. Endotracheal intubation was accomplished using videolaryngoscopy to confirm placement. The endotracheal tube was not connected to the breathing circuit, and patients were allowed to be apneic. Ventilation was resumed when Spo_2 reached 94%. We defined ORI warning time as the time from when the ORI alarm registered (based on the absolute value and the rate of change) until the Spo_2 decreased to 94%. We defined the Spo_2 warning time as the time for Spo_2 to decrease from 97% to 94%. The added warning time provided by ORI was defined as the difference between ORI warning time and Spo_2 warning time.

RESULTS: Forty subjects were enrolled. Complete data for analysis were available from 37 patients. The ORI alarm registered before Spo_2 decreasing to 97% in all patients. Median (interquartile range [IQR]) ORI warning time was 80.4 seconds (59.7–105.9 seconds). Median (IQR) Spo_2 warning time was 29.0 seconds (20.5–41.0 seconds). The added warning time provided by ORI was 48.4 seconds (95% confidence interval [CI], 40.4–62.0 seconds; $P < .0001$).

CONCLUSIONS: In adult high-risk surgical patients, ORI provided clinically relevant added warning time of impending desaturation compared to Spo_2. This additional time may allow modification of airway management, earlier calls for help, or assistance from other providers. The potential patient safety impact of such monitoring requires further study. (Anesth Analg XXX;XXX:00–00)

KEY POINTS

- **Question:** Can the Oxygen Reserve Index (ORI), a parameter derived from multiwavelength oximetry analysis, provide advanced warning of developing hypoxemia?
- **Findings:** When compared to a pulse oximetry hemoglobin saturation (Spo_2) trigger of 97%, the ORI alarm provided an advanced warning time of over 45 seconds in high-risk surgical patients.
- **Meaning:** The advance warning provided by the ORI monitor may allow sufficient time for modification of a difficult airway management plan.

GLOSSARY

ASA = American Society of Anesthesiologists; **BMI** = body mass index; **CABG** = coronary artery bypass grafting; **CE** = Conformitè Europëenne; **CI** = confidence interval; **IQR** = interquartile range; **ORI** = Oxygen Reserve Index; **Pao_2** = partial pressure of oxygen; **Pco_2** = partial pressure of carbon dioxide; **Sao_2** = arterial oxygen saturation; **Spo_2** = pulse oximetry hemoglobin saturation; **UC** = University of California; **USB** = universal serial bus; **WHO** = World Health Organization

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Intraoperative monitoring of hemoglobin saturation using pulse oximetry (Spo_2) has revolutionized anesthetic practice.[1–3] Advances in pulse oximetry signal processing have improved sensitivity, decreased motion artifact and response times, and improved accuracy in low perfusion states. While studies of pulse oximetry have not found a benefit, its use decreases the likelihood of hypoxemia.[2,4,5] However, Spo_2 monitoring is limited by the sigmoidal relationship between arterial oxygenation (partial pressure of oxygen [Pao_2]) and Spo_2.[3,6] Because large changes in Pao_2 above a certain threshold cause only small changes in Spo_2, when Pao_2 is falling, the Spo_2 may not reflect that trend until the Pao_2 falls below approximately 80 mm Hg.[7–9] Increasing the number of wavelengths analyzed allows quantitative measurement of methemoglobin, carboxyhemoglobin, and total hemoglobin.[10] One additional output of multiple wavelength analysis is the Oxygen Reserve Index (ORI) which is provided by a multiwavelength pulse oximeter produced by Masimo, Inc (Irvine, CA). The algorithm is based on data from 8 wavelengths ranging between 500 and 1400 nm and is currently Conformitè Europëenne (CE) marked and commercially available in over 150 countries (but not in the United States).[11–13]

As previously published, the ORI is a nondimensional parameter that ranges between 0 and 1. ORI values reflect arterial oxygen concentrations in the moderately hyperoxic region (between 100 and 200 mm Hg).[11,12] The ORI provides information on changes in oxygenation when standard pulse oximetry measurements read 100%.[14] The ORI provides advanced warning of impending desaturation in a variety of clinical settings including rapid sequence induction,[15] pediatric intubations,[13] thoracic surgery during one-lung ventilation,[16] or tracheal stent placement requiring interruption of ventilation.[17] Performance of the ORI during prolonged apnea in high-risk surgical patients presents another potential clinical application. Patients undergoing airway surgery or in whom airway management is difficult may require prolonged periods of apnea during which oxygen desaturation may occur. Effectively predicting when patients may desaturate may help surgeons and anesthesia care providers more safely accomplish procedures that require apnea. High-risk surgical patients may desaturate more rapidly than healthy patients because of factors including increased alveolar-arterial oxygen gradients, increased shunt fraction, alterations of functional residual capacity, and increased oxygen consumption.[18] This study was designed to evaluate the potential for ORI to provide clinically significant additional warning time for arterial desaturation during apnea in high-risk surgical patients.

METHODS

The protocol was reviewed and approved by the University of California (UC) Davis Institutional Board overseeing human subjects research and listed on ClinicalTrials.gov (NCT03021473). Written informed consent was obtained from all patients enrolled in this study. This was a prospective, nonblinded, nonrandomized, observational study of ORI in adult patients of American Society of Anesthesiologists (ASA) physical status III or IV who were scheduled for elective surgical procedures requiring endotracheal intubation with planned arterial pressure monitoring placed before induction of general anesthesia. Exclusion criteria included age <18 years, inability to give primary consent, pregnancy, and prisoner status. Nonpregnant women, minorities, and non–English-speaking subjects were not excluded. Pragmatically, the study population comprised predominantly of patients scheduled for elective cardiac surgical procedures as these high-risk surgical patients routinely have arterial pressure monitoring placed before anesthesia induction at our institution.

No restrictions were placed on perioperative anesthetic care. Generally, management included administration of intravenous premedication and subsequent patient transport to the operating room and positioning on the operating table. Standard physiological monitors were placed. All patients had radial arterial catheters placed before induction of anesthesia. In addition, an ORI oximetry sensor (Masimo Rainbow Disposable RD Lite; Masimo Inc, Irvine, CA) was placed on a finger, covered with an opaque shield to prevent exposure to ambient light and connected to a Masimo Root monitor. A universal serial bus (USB) data output port on the Root monitor was connected to a computer (HP ProBook 640; Hewlett-Packard, Palo Alto, CA) running proprietary Pulse Oximetry Automatic Data Collection software (V3.2.2.0; copyright Masimo Inc, 2015) to create and store data files that were subsequently analyzed offline. The Masimo Root monitor contained the ORI measurement software. A detailed explanation of the relationship between pulse oximetry and ORI appears as an appendix to the initial clinical presentation of this parameter.[13] ORI is a novel, multiwavelength pulse oximeter–based, nondimensional index that ranges from 0 to 1 as Pao_2 increases from about 80 to 200 mm Hg. The ORI is based on the Masimo Rainbow SET (Masimo Inc, Irvine, CA) technology in which the pulsatile signals are extracted from 8 wavelengths ranging between 500 and 1400 nm, enabling detection of changes in Pao_2 after arterial oxygen saturation (Sao_2) is maximally saturated based on changes in the peripheral venous oxygen saturation. Specifically, as Pao_2 increases beyond 100 mm Hg, peripheral venous oxygen saturation continues to increase, even though Sao_2 has effectively saturated at 100%. This modest increase

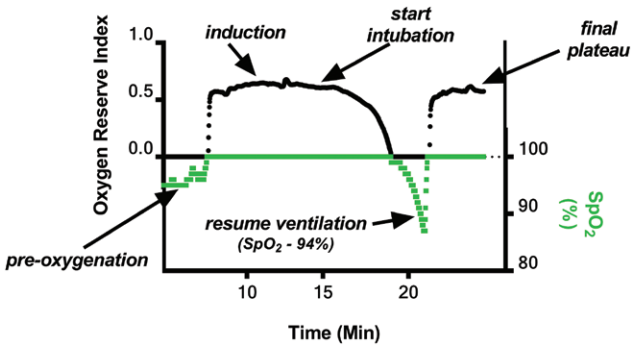

Figure 1. Illustration of patient care events and corresponding time points at which Spo_2 (green line) and Oxygen Reserve Index (black line) values were recorded. Spo_2 indicates pulse oximetry hemoglobin saturation.

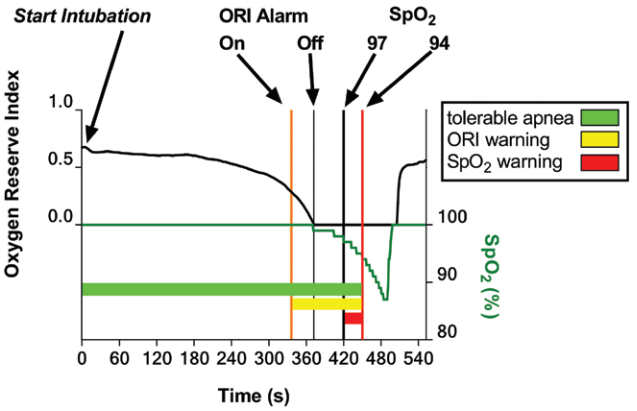

Figure 2. Illustration of typical patient showing defined times: tolerable apnea time was from the start of intubation to Spo_2 reaching 94%; ORI warning time was from the onset of the ORI alarm to Spo_2 reaching 94%; and Spo_2 warning time was from Spo_2 97% to Spo_2 reaching 94%. Added ORI warning time is the difference between ORI and Spo_2 warning times. ORI indicates Oxygen Reserve Index; Spo_2, pulse oximetry hemoglobin saturation.

in peripheral venous oxygen saturation above its normal value of approximately 75% will eventually stop as Pao_2 reaches significantly higher values (ie, >200 mm Hg). The ORI algorithm builds from the Fick principle which relates oxygen consumption to cardiac output and the difference between arterial and venous oxygen content. With appropriate mathematical substitutions and a constant cardiac output and oxygen consumption, peripheral venous oxygen saturation is directly proportional to Pao_2. Potential confounding factors consequently include cardiac output, oxygen consumption, blood pH, partial pressure of carbon dioxide (Pco_2), temperature, the amount of perfusion (venous pulsation), and the presence of abnormal hemoglobins.

Hemodynamic and oximeter data were continuously monitored. ORI and Spo_2 were specifically recorded at 5 time points (Figure 1). Baseline values were recorded before preoxygenation. As per routine, patients were then preoxygenated with 100% oxygen. At the end of preoxygenation, when ORI values had plateaued for at least 30 seconds, a second set of values was recorded. General anesthesia was then induced with a combination of amnestics, narcotics, intravenous induction agents, and muscle relaxants as clinically indicated. With mask ventilation using 100% oxygen and a stable ORI, a third set of values was recorded immediately before initiating laryngoscopy. Endotracheal intubation was performed under direct visualization using a GlideScope (Verathon Inc, Bothell, WA) to confirm position. Following placement, the endotracheal tube was not connected to the anesthesia circuit and the patient was allowed to be apneic. No ventilation occurred until Spo_2 reached 94% at which time a fourth set of values was recorded and ventilation was initiated with 100% oxygen via the endotracheal tube. A final postinduction set of values was recorded 5 minutes following initiation of controlled ventilation with 100% oxygen. Arterial blood gas analysis was performed at each of these same 5 time points using a point-of-care analyzer (Epoc Reader, v 3.30.2; Epocal, Inc, Ottawa, Ontario, Canada): baseline, end of preoxygenation, start of intubation, end of apnea (Spo_2 = 94%), and after 5 minutes of controlled ventilation.

Comparisons of warning times provided by the ORI and Spo_2 were based on the elapsed times to specified events. For this study, we defined tolerable apnea as the time from the discontinuation of mask ventilation and start of laryngoscopy until Spo_2 decreased to 94%. The ORI warning time was defined as the time from the onset of the ORI alarm (triggered by the fractional rate of change) until Spo_2 decreased to 94%. Spo_2 warning time was defined as the time from Spo_2 = 97% until Spo_2 decreased to 94%. The added warning time provided by ORI was defined as the difference between ORI warning time and Spo_2 warning time (Figure 2).

Statistical Analysis

The primary outcome was the difference in warning time from the ORI and Spo_2. This continuous time data were determined to not be normally distributed by examination of the histograms and the D'Agostino–Pearson normality test. Times are therefore reported as median (interquartile range [IQR], 25th to 75th percentile). Comparisons between ORI warning time (ORI alarm to Spo_2 94%) and Spo_2 warning time (Spo_2 97% to Spo_2 94%) were made using the paired Wilcoxon signed rank test, with the Hodges–Lehmann estimate for differences. Comparisons of Pao_2 values utilized analysis of variance and Dunn multiple comparison test. All statistical analysis was performed using Prism (version 8.2.1; GraphPad Software, Inc, San Diego, CA).

To calculate the sample size needed to assess added warning time from ORI in critically ill patients, we extrapolated from a report that measured the time for arterial hemoglobin saturation to decrease from 98% to 90%.[13] We considered a clinically significant improvement to be

Table. Patient Characteristics

Enrolled and Analyzed	n = 37
Sex n (%)	
Female	12 (32.4%)
Male	25 (67.6%)
Age (y) ± SD	60.8 ± 9.7
BMI ± SD	30.1 ± 6.7
Surgical procedure	
Valve repair/replace alone or combined	23 (62%)
CABG	8 (22%)
Other cardiac or major vascular	6 (16%)
ASA classification n (%)	
III	4 (10.8%)
IV	33 (89.2%)
EuroScore (median) (25th to 75th percentile)	3.81 (1.61 to 7.86)

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; CABG, coronary artery bypass grafting; SD, standard deviation.

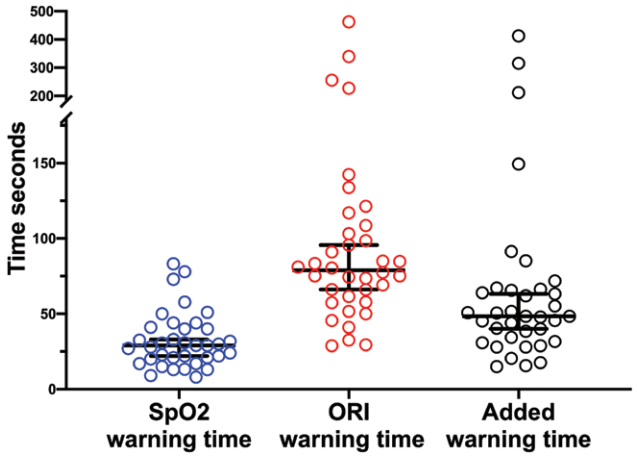

Figure 3. Comparison of warning time from Spo_2 (time for Spo_2 to decrease from 97% to 94%) and ORI (time from ORI alarm onset to Spo_2 reaching 94%). The added warning time provided by ORI compared to Spo_2 was median 48.4 seconds (95% CI, 40.4–62.0 seconds); $P < .0001$. ORI indicates Oxygen Reserve Index; Spo_2, pulse oximetry hemoglobin saturation.

30 seconds of added warning time. In this trial,[13] the time for the hemoglobin saturation to reach 98% was 10.3 ± 2.5 minutes and the time for the hemoglobin saturation to decrease to 90% was 11.2 ± 2.4 minutes. Based on this reported mean and standard deviation, with a power of 0.8, and α of .05, the estimated required sample size for a group *t* test comparison was 34 patients. We increased the planned sample size to 40 to allow for incomplete data collection and potential dropouts.

RESULTS

Written informed consent was obtained from 40 patients. In 3 patients, the automatic data collection program failed, leaving 37 data sets for analysis. Patient characteristics are shown in the Table. The majority of these patients (89%) were ASA class IV. For additional risk characterization, their average EuroScore was 5.8 ± 6.3 and ranged from 0.6 to 32 (median: 3.8; 25th to 75th percentile, 1.6 to 7.9). The average time of tolerable apnea (start of intubation to Spo_2 94%) was 9.6 ± 2.2 minutes and ranged from 5 to 14 minutes. The ORI alarm occurred before Spo_2 decreasing to 97% in all patients. As shown in Figure 3, the median time (IQR) from ORI alarm to Spo_2 94% was 80.4 seconds (59.7–105.9 seconds). In comparison, the median time (IQR) from Spo_2 97% to Spo_2 94% was 29.0 seconds (20.5–41.0 seconds). The median added warning time provided by ORI was 48.4 seconds (95% confidence interval [CI], 40.4–62.0 seconds; $P < .0001$).

For these comparisons, we used the ORI alarm included with the measurement software. This alarm is based on a proprietary algorithm that is based on both the absolute ORI value and fractional rate of change. Figure 4 illustrates the performance of this alarm in a spectrum of clinical scenarios including a

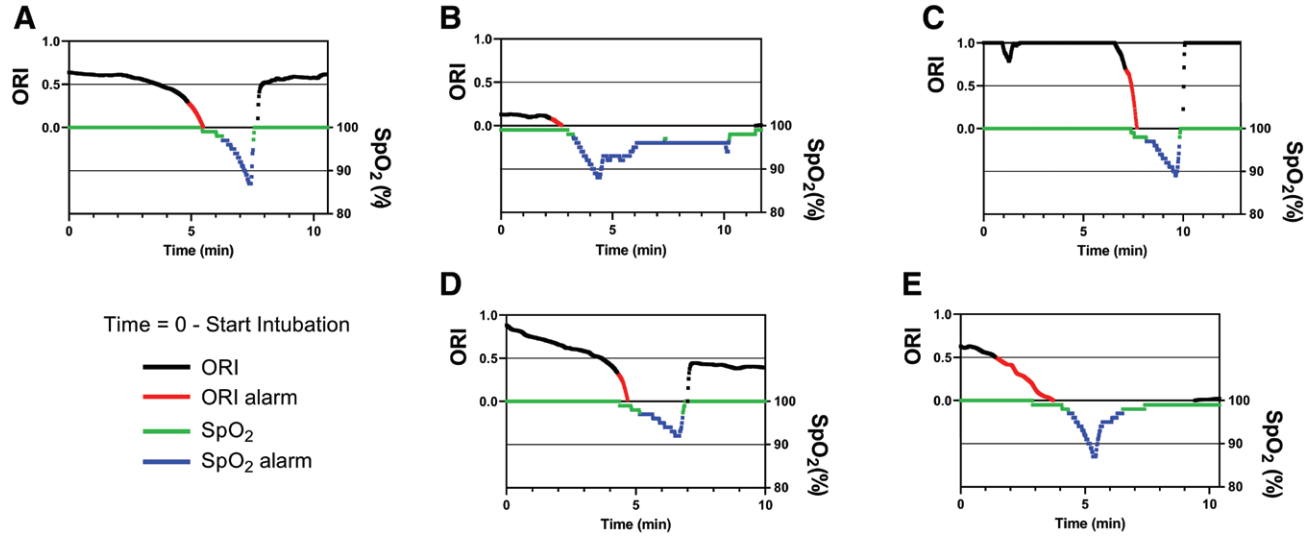

Figure 4. Examples of ORI alarm performance in a variety of patients from this study. A, ORI and Spo_2 changes in a typical patient from this protocol. B, ORI alarm activation with a low ORI plateau value. C, ORI alarm activation with a maximal (ORI = 1) value before and after apnea. D, ORI alarm activation with a gradual rate of decline and an acute increased rate of change. E, ORI alarm activation with a gradual rate of decline and no obvious increased rate of change. ORI indicates Oxygen Reserve Index; Spo_2, pulse oximetry hemoglobin saturation.

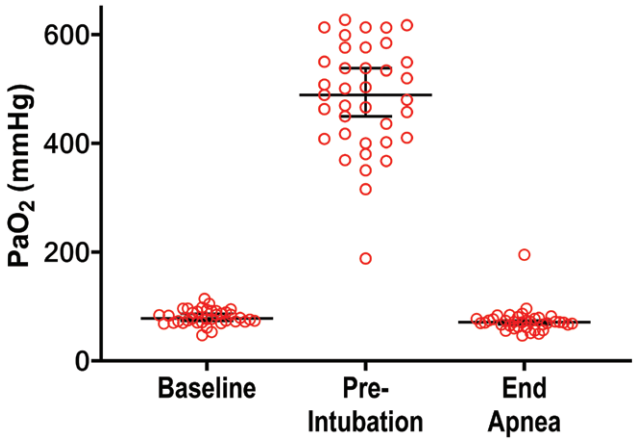

Figure 5. Comparison of Pao_2 at baseline, at the start of intubation, and at the end of apnea. Pao_2 increased significantly following preoxygenation and mask ventilation with 100% oxygen before intubation. Pao_2 was lower at the end of apnea than at baseline (difference, 8; 95% CI, −15 to −1 mm Hg; $P = .03$). Pao_2 indicates partial pressure of oxygen.

typical recording as well as patients with a low maximal ORI value and an ORI = 1 as maximum. The rate of decline of the ORI did vary among patients, and the last 2 panels demonstrate alarm performance with a gradual decline that accelerates and one that maintains a gradual decline throughout.

The baseline Pao_2 (median, 72; IQR, 81 to 114 mm Hg) increased before the start of intubation (median, 484; IQR, 409 to 550 mm Hg). Pao_2 values at the end of apnea (Spo_2 = 94%) (median, 71; IQR, 65 to 77 mm Hg) did not differ from those measured at baseline. The difference between baseline and end of apnea Pao_2 was 8 mm Hg (95% CI, −15 to −1 mm Hg; $P = .03$) (Figure 5).

DISCUSSION

In this study of prolonged apnea in high-risk surgical patients undergoing elective cardiac surgery, we found that using a multiwavelength pulse oximeter to measure ORI provides earlier warning of serious oxygen desaturation when compared to conventional pulse oximetry. In patients allowed to be apneic after induction of general anesthesia and intubation until hemoglobin saturation fell to 94%, the ORI detected impending desaturation a median of 48 seconds earlier. Our findings suggest that the additional warning time provided by ORI is sufficient to allow clinicians to constructively intervene before critical desaturation events during prolonged apnea. This advanced warning time may reduce the incidence of critical desaturation events.[8]

Our findings are consistent with previous studies of oxygen desaturation. In our study group, the tolerable apnea time duration varied widely, from 5 to 14 minutes.[19,20] However, the ORI alarm consistently preceded decreases in Spo_2, similar to its behavior in previous studies.[13,16]

In the initial clinical report of ORI in 2016, a postintubation apnea design was used in children to compare the ORI to standard pulse oximetry. The ORI provided a median warning time of 31 seconds from the time of the alarm to a decline in Spo_2 to 98%.[13] Another 2018 test of ORI using one-lung ventilation found that the time required for ORI to fall by 5% was 171 seconds, whereas the time required for Spo_2 to decrease 1% from baseline was nearly twice as long.[16] Yoshida et al[15] compared the changes in ORI and Spo_2 following a rapid sequence induction in adults to characterize the advanced warning potential of the ORI.

Our findings have clinical implications. The value of ORI in prolonged apnea such as for airway surgery or with difficult airway management has been hinted at in clinical reports of the ORI in tracheal stent placement requiring extended apnea[17] and during repair of a neonatal tracheal–esophageal fistula requiring repeated periods of apnea.[21] Our current study systematically tested a scenario similar to these reports. Our patients were apneic for 6 minutes before the ORI alarmed. This duration is likely longer than that needed for uncomplicated airway management, but easily in the range required for difficult airway management or airway surgery. In both situations, early warning via the ORI may allow surgeons to better plan their interventions and anesthesiologists to choose optimal airway management strategies.

Although the ORI does not directly measure Pao_2, existing data suggest good correlation. A 2016 comparison of intraoperative Pao_2 and ORI values found a correlation coefficient of 0.56 for Pao_2 <240 mm Hg.[11] Vos et al[14] further evaluated the correlations between ORI and Pao_2 in healthy volunteers breathing inspired oxygen concentrations varying between 14% and 100% and likewise found a strong correlation.

Several limitations to this study should be noted. For this analysis, we selected the transition from 98% to 97% as the trigger for the Spo_2 alarm. This subjective decision was guided by the accuracy of the Spo_2 measurement and the observation that in the setting of apnea, the decrease to 97% was consistently followed by further decreases. For comparison, we calculated the impact of increasing this trigger from 97% to 98% and observed a decrease in the median ORI/Spo_2 warning time difference from 48.4 to 29.4 seconds (95% CI, 23.8–39.0 seconds). Similarly, we defined the warning time to end at 94% Spo_2. Prior studies have defined the duration of tolerable apnea to end at 90% Spo_2. We chose this target in part due to the World Health Organization (WHO) designation of an Spo_2 of 94% as a trigger for intervention,[22] even though in many clinical situations this Spo_2 might

not be considered to be critical. Second, we used the ORI alarm as the start of the advanced warning to provide the most consistent and clinically relevant assessment. The trigger for initiation of this alarm is a proprietary algorithm based on both the absolute ORI value and the fractional rate of decline. Examples of alarm performance are provided in Figure 4. Other studies have used retrospective, offline analysis of either percentage or absolute value changes in the ORI as the start of the advanced warning. Although this might increase the absolute advanced warning time provided by the ORI, and perhaps decrease the number of outlier measurements, the comparative relationship to the Spo_2 warning would be similar. Additionally, we encountered a small, but significant data collection system failure rate. This was felt most likely to reflect the constraints encountered in a clinical trial. Time pressures to proceed with anesthetic management did not allow for system troubleshooting required to initiate the ORI measurements. Also, in this protocol, we did not intervene with respect to clinical management based on changes in ORI. This protocol was constructed to provide clinically relevant information while maintaining patient safety. Therefore, we are not able to actually determine the impact ORI guidance might have on intraoperative desaturation events which often occur without the safety net of controlled preoxygenation and established airway access. Lastly, we did not specifically study the correlation between ORI and Pao_2. Consequently, any recommendations regarding the use of ORI in other patient types, as a guide to preoxygenation or the potential utility for avoiding hyperoxia remain as areas for future study, not specifically addressed in this study design.

In conclusion, ORI provided clinically relevant additional warning time in advance of impending desaturation compared to Spo_2 during prolonged apnea in high-risk patients undergoing elective cardiac surgery. The additional warning time may allow clinicians to better manage prolonged apneic periods due to airway surgery or difficult airway management. The potential patient safety impact of such guided interventions requires further study.

DISCLOSURES

Name: Neal W. Fleming, MD, PhD.
Contribution: This author helped design the study; collect, analyze, and interpret the data; draft and revise the manuscript; and approve the final version of the manuscript.
Conflicts of Interest: N. W. Fleming has received research support from Masimo.
Name: Amrik Singh, MD.
Contribution: This author helped collect, analyze, and interpret the data; revise the manuscript; and approve the final version of the manuscript.
Conflicts of Interest: None.
Name: Leonard Lee, MD.
Contribution: This author helped collect, analyze, and interpret the data and approve the final version of the manuscript.
Conflicts of Interest: None.
Name: Richard L. Applegate II, MD.
Contribution: This author helped design the study, analyze, and interpret the data; draft and revise the manuscript; and approve the final version of pt.
Conflicts of Interest: R. L. Applegate has received research support from Masimo, has served as a consultant to Masimo, and has received honoraria from Masimo for presentations.
This manuscript was handled by: Avery Tung, MD, FCCM.

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