

## **Title page**

### **Contribution of Oxygen Reserve Index monitoring to the early detection of deterioration of blood oxygenation by one lung ventilation**

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## Abstract

**Background.** Hypoxemia associated with one-lung ventilation (OLV) is possible incident in anesthesia. Although percutaneous oxygen saturation (SpO<sub>2</sub>) is important in monitoring of blood oxygenation, it has detection latency and does not change in some cases regarding OLV. The oxygen reserve index (ORi™) (Masimo Corp., Irvine, CA, USA) is a novel index reported to detect impending desaturation earlier than SpO<sub>2</sub>. We assessed whether the ORi declines earlier than SpO<sub>2</sub> in OLV and evaluated the correlation between the ORi and partial pressure of arterial oxygen (PaO<sub>2</sub>) during OLV.

**Methods.** The study enrolled 15 patients (ASA 1-2) undergoing elective thoracic surgery. The tracheae were intubated with a left-sided double-lumen endotracheal tube. After the lungs were mechanically ventilated in pressure-control mode for 10 minutes, with the fraction of inspired oxygen (FiO<sub>2</sub>) set at 0.6, right OLV was initiated for 15 minutes or until SpO<sub>2</sub> declined to 91%. The ORi and SpO<sub>2</sub> were monitored and data were stored continuously. PaO<sub>2</sub> was measured 5 minutes before and every 3 minutes during OLV and these values were analysed. Time from start of OLV to start of a decline is expressed as mean (1SD).

**Results.** The ORi declined significantly earlier than SpO<sub>2</sub> [ORi vs. SpO<sub>2</sub>: 171 (102) vs. 372 (231) seconds;  $P < 0.01$ ]. The ORi and PaO<sub>2</sub> showed a significant and strong correlation ( $r^2 = 0.671$ ,  $P < 0.01$ ).

**Conclusions.** The ORi decreased earlier than SpO<sub>2</sub> in OLV, which might contribute to the early detection of deterioration of blood oxygenation by OLV.

**Keywords:** Oxygen Reserve index, ORi, SpO<sub>2</sub>, endobronchial intubation, one lung ventilation

## Introduction

Hypoxemia due to one-lung ventilation (OLV) has a significant incidence in anesthesia and intensive care.<sup>1, 2</sup>

In scheduled OLV, e.g. in the thoracic surgery, latency of inflation of the lung on the operating side to recover SpO<sub>2</sub> results in exposing patients to hypoxemia.<sup>1</sup> In unscheduled OLV such as accidental endobronchial intubation (EBI) associated with intraperitoneal insufflation or head flexion which can lead to pneumothorax or large atelectasis formation during general anesthesia, also could result in hypoxemia during or after surgery.<sup>2, 3</sup>

Although percutaneous oxygen saturation (SpO<sub>2</sub>) plays an important role in the detection of hypoxemia caused by OLV,<sup>4, 5</sup> there is detection latency.<sup>3, 6</sup> Furthermore, it has been pointed out that pulse oximetry may not consistently detect it at a fraction of inspired oxygen (FiO<sub>2</sub>) of 0.5 or greater, or may not detect it with certainty even at an FiO<sub>2</sub> of 0.3.<sup>4, 7</sup>

The oxygen reserve index (ORi™) (Masimo Corp., Irvine, CA, USA) is a novel pulse oximeter-based non-dimensional index, ranging from 1 (much reserve) to 0 (no reserve) (Fig. 1).<sup>8, 9</sup> A previous study showed a positive correlation between the ORi and PaO<sub>2</sub> when PaO<sub>2</sub> was 240 mmHg or lower ( $r^2 = 0.536$ ),<sup>10</sup> and it was shown that the ORi detected impending desaturation before SpO<sub>2</sub> began to decline in adult and pediatric patients during induction of anesthesia.<sup>9, 11</sup>

ORi monitoring might contribute to the early detection of the deterioration of blood oxygenation by OLV. In this study, we assessed whether the ORi declines earlier than SpO<sub>2</sub> on OLV. We also evaluated the correlation between the ORi and PaO<sub>2</sub>.

## Materials and methods

This study was approved by the ethics committee of Iwate Medical University Hospital, Japan, and it was registered in the UMIN Clinical Trials Registry (UMIN000026218). After obtaining written informed consent, we enrolled 15 consecutive patients undergoing elective thoracic surgery, which requires one-lung ventilation (OLV) during surgery.

Routine monitoring, including electrocardiography and non-invasive automated blood pressure (NIBP) measurement, was started on arrival in the operating room. Additionally, a sensor for measuring the ORi and SpO<sub>2</sub> (Rainbow<sup>®</sup> sensor, R2–25, Revision L, Masimo Corp.) was applied to the index or middle finger on the contralateral side of the inflatable cuff for NIBP monitoring, and a light-shielding cover was applied to the sensor. SpO<sub>2</sub> and ORi values were displayed and stored on Root<sup>®</sup> with Radical-7<sup>®</sup> (Masimo Corp.).

Anesthesia was induced by effect site target-controlled infusion (TCI) of propofol (5 µg·ml<sup>-1</sup>) and remifentanyl (0.2–0.4 µg·kg<sup>-1</sup>·min<sup>-1</sup>). After administering rocuronium (0.8 mg·kg<sup>-1</sup>), the tracheae were intubated with a 35-French left-sided double-lumen endotracheal tube (Shiley<sup>™</sup> Endobronchial Tube, COVIDIEN, Minneapolis, MN, USA), and correct positioning was verified through fiberoptic bronchoscopy. Then, a radial artery catheter was inserted for direct arterial blood pressure measurement and blood sampling.

After mechanically ventilating the lungs in pressure-control mode (PCV) for 10 minutes, right OLV without opening the left-side lumen to the atmosphere, was initiated for 15 minutes or until SpO<sub>2</sub> declined to 91%. During these procedures, the FiO<sub>2</sub> was set at 0.6, and the peak inspiratory pressure (PIP) was set at 12–15 cm H<sub>2</sub>O with a PEEP of 3 cm H<sub>2</sub>O. Additionally, the respiratory frequency (RF) was adjusted to maintain the end-tidal carbon dioxide tension (EtCO<sub>2</sub>) between 4.7 and 5.3 kPa, and the concentration of propofol maintained by TCI was adjusted to achieve a bispectral Index (BIS) of 40–60. Moreover, remifentanyl was adjusted to maintain a systolic arterial pressure (SAP) of 80–140 mm Hg. When the SAP decreased to ≤80 mmHg, it was treated with an 8-mg bolus of ephedrine. Blood gas analysis was performed 5 minutes before and every 3 minutes after OLV. The responsible anesthesiologist was blinded to the ORi but not the SpO<sub>2</sub> values. All of these measurements were performed in the supine position.

The collected ORi and SpO<sub>2</sub> data were analysed offline by the investigator after surgery. The data were stored every 2 seconds, and the median of every 10 seconds (5 values) was used for analysis. The definitions of the time of the start of a decline were as follows: (a) ORi, only values of 0.05 less than the highest value after OLV; (b) SpO<sub>2</sub>, only values of 1% less than the highest value after OLV.

Data are presented as mean (1SD) for normally distributed values and as median

[interquartile range] for non-normally distributed values. Based on a pilot study, the sample size was calculated to detect a 303-second difference in the mean time of the start of a decline between the ORi and SpO<sub>2</sub>, with 105 (56) seconds for the ORi compared with 408 (232) seconds for SpO<sub>2</sub>, using G power. The power analysis indicated that a minimum sample size of 6 patients was needed to detect an effect size of 1.4 using dependent Student's *t*-test with a two tailed  $\alpha$  error probability of 0.05 and a power of 0.80. Thus, we aimed to include 15 patients to allow the drop-out. The Shapiro–Wilk test was used to assess the normality of the data. Dependent Student's *t*-tests were used to compare the mean time of the start of a decline between the ORi and SpO<sub>2</sub>. The correlation between the ORi and PaO<sub>2</sub> was evaluated through simple linear regression. All statistical tests were two-tailed. Significance was determined at a *P*-value <0.05, and all analyses were performed using XLSTAT 2015 for Windows (Addinsoft, New York, NY, USA).

## Results

The patient characteristics are presented in Table 1. Respiratory function data and complications of all patients are presented in Table 2. There were 6 patients (Pt. 3, 6, 7, 8, 9, 12) with chronic obstructive pulmonary disease (COPD) defined as  $<70\%$  of FEV1% and 7 smoker patients (Pt. 3, 7, 8, 9, 11, 12, 13) defined as  $\geq 300$  of Brinkman Index. We assessed 15 patients for eligibility to participate in this study, and all patients met the inclusion criteria and did not decline to participate. In two cases, OLV was discontinued before 15 minutes had passed because of the decrease in SpO<sub>2</sub> to 91%. No adverse events occurred in any of the patients, and no patients were excluded from the study and final analysis.

The time from the start of OLV to the start of declines in SpO<sub>2</sub> and ORi were normally distributed. The SpO<sub>2</sub>, ORi, PaO<sub>2</sub>, and PaCO<sub>2</sub> values were not normally distributed. The time courses for the changes in the ORi and SpO<sub>2</sub> are shown in Fig. 2, changes in PaO<sub>2</sub> and PaCO<sub>2</sub> are shown in Fig. 3, changes in the ORi, PaO<sub>2</sub>, and PaCO<sub>2</sub> in each patient are shown in Fig. 4. The ORi began to decrease significantly earlier than SpO<sub>2</sub> with the start of OLV [ORi vs. SpO<sub>2</sub>: 171 (102) seconds vs. 372 (231) seconds, mean time from start of OLV to start of a decline;  $P < 0.01$ ].

A total of 101 paired measurements of ORi and PaO<sub>2</sub> during OLV were compared using linear regression, which showed a significant and strong correlation ( $r^2 = 0.67$ ,  $P < 0.01$ ) (Fig. 5).

## Discussion

The current study is the first to investigate the difference in the reaction to OLV between ORi and SpO<sub>2</sub>, and it was found that the ORi begins to decline significantly earlier than SpO<sub>2</sub>, with a mean difference of about 200 seconds. It was also found that the ORi and PaO<sub>2</sub> were highly correlated during OLV.

ORi and PaO<sub>2</sub> show a wide variance after OLV on Fig. 2 and Fig. 3. This is because the range of values of ORi were actually wide reflecting PaO<sub>2</sub> and values are expressed as median [third quartile], not as mean (1SD) due to their non-normally distribution. There were dispersions of ORi to the same values of PaO<sub>2</sub> among patients and vice versa. In case of PaO<sub>2</sub> of around 260 mmHg, ORi was 0.24 to 269 mmHg in Pt. 8, 0.37 to 265 mmHg in Pt. 4, and 0.61 to 264 mmHg of PaO<sub>2</sub> in Pt.6, respectively. In case of 0.3 of ORi, PaO<sub>2</sub> was 170 mmHg in Pt. 13 and 232 mmHg in Pt. 14. Trend of change in ORi and PaO<sub>2</sub> seems to be similar, but some deviations can be seen, for example, in 1 minute after OLV in Pt. 7, 3.5 and 7 minutes after OLV in Pt. 9, and 4.5 minutes after OLV in Pt. 12. These temporary deviations took about 30 seconds to recover. Therefore, we should consider not only the absolute value itself but also the trend of the ORi and the respiratory conditions.

Applegate et al. showed that the correlation between ORi and PaO<sub>2</sub> values was high when PaO<sub>2</sub> was 240 mmHg or lower ( $r^2 = 0.536$ ).<sup>10</sup> We also showed a high correlation between ORi and PaO<sub>2</sub> during OLV ( $r^2 = 0.671$ ). It is helpful that we can easily obtain the value highly related to PaO<sub>2</sub> during the detection and correction of airway problems, where securing the airway is of high priority because arterial blood gas analysis takes a long time, even when the arterial line is already secured.<sup>11</sup> In the current study, the FiO<sub>2</sub> was set at 0.6 and PaO<sub>2</sub> was under 240 mmHg in 68 of the 101 pairs. Because the majority of PaO<sub>2</sub> values analysed were under 240 mmHg, a high correlation would be observed.

We aimed to establish the protocol in which ORi can make a significant contribution in clinical use, hence, we chose the PCV where unscheduled OLV cannot be detected easily due to the useless of high pressure alarm. To duplicate the normal clinical use in unscheduled OLV, the responsible anesthesiologist controlled the PIP and RF guided only by EtCO<sub>2</sub> keeping it normal range and PaCO<sub>2</sub> increased gradually after OLV. PaCO<sub>2</sub> just before OLV was 36.7 (3.1) mmHg and at the highest value after OLV was 46.8 (3.9) mmHg, respectively.

There is no universally accepted cut-off value of the ORi that indicates a significant decline. In previous studies, Szmuk et al. used this built-in alarm,<sup>11</sup> whereas Yoshida et al. defined the time at which the ORi decreased by 0.05 from the peak value as the point when the ORi began to decline because the ORi typically fluctuates within a range of  $\pm 0.02$ , and they

considered a decline of 0.05 to be large enough to recognise the start of ORi decline,<sup>9</sup> which was also used in the current study.

Findings of the current study might contribute to several kinds of situation. In case of EBI, each of the already proposed techniques used for the identification has flaws and limitations.<sup>12-16</sup> When simply applying the findings of current study to EBI, the advantage of the ORi (detection about 200 seconds earlier) might considerably shorten the time of diagnosis and correction, which took 484 (347) seconds mostly contributed by monitoring of SpO<sub>2</sub> according to the previous study.<sup>17</sup>

In some cases, SpO<sub>2</sub> did not change or was within the normal range despite OLV.<sup>7</sup> Because pulse oximetry plays an important role in the detection of those,<sup>4, 17</sup> its normal value can prevent detection. There were two such cases in the current study. In Pt. 14, SpO<sub>2</sub> was 100% during 15 minutes of OLV, whereas the ORi declined from 0.40 to 0.16. In Pt. 12, SpO<sub>2</sub> was 97% 15 minutes after OLV, whereas the ORi declined from 0.43 to 0.00. These findings suggest that the ORi provides an opportunity to detect the deterioration of oxygenation, which cannot be detected by SpO<sub>2</sub> alone.

The current study has several limitations. First, because PIP and RF were changed irregularly guided only by EtCO<sub>2</sub> under PCV, detail of these and tidal volume could not be recorded. Furthermore, a sampling interval of blood gas was 3 minutes. More detailed and frequent information about these would contribute to better understanding about the ORi. Second, the factors accounting for dispersions or deviations of ORi cannot be detected. Respiratory function and complications of each patient does not seem to be the factor. Furthermore, the patients with pneumothorax, interstitial pneumonia, ischemic heart or cerebral disease, deformity or hypoperfusion of the fingers, haemoglobinopathies (i.e. sickle cell disease and thalassemia), and patients under 20 years of age were not included as an exclusion criteria in the current study. Further research on many different types of patients are needed to clear these aspects. Third, we did not evaluate left-sided OLV. PaO<sub>2</sub> was significantly higher during right-sided than left-sided OLV.<sup>18</sup> Although it was predicted that the ORi decreased prior to the decrease in SpO<sub>2</sub> in left-sided OLV, their actual extent should be evaluated separately. Fourth, we performed assessments only under the respiratory condition of FiO<sub>2</sub> at 0.6. The ORi declines but SpO<sub>2</sub> does not when oxygenation is in the moderate hyperoxic range (PaO<sub>2</sub> 100–240 mm Hg).<sup>10</sup> PaO<sub>2</sub> at the occurrence of OLV was lower within this range, and the time difference to the start of a decline between ORi and SpO<sub>2</sub> was predicted to be shorter. In the current study, of the 15 cases, PaO<sub>2</sub> at the occurrence of OLV was over 240 mmHg in 13 cases. If tested under a condition of FiO<sub>2</sub> lower than 0.6, the preceding time of ORi to SpO<sub>2</sub> might be shorter.



## Conclusions

The ORi declined earlier than SpO<sub>2</sub> significantly after the start of OLV. Although this finding suggests that monitoring trends in the ORi and SpO<sub>2</sub> might allow earlier assessment of the deterioration of blood oxygenation, which might contribute to a reduction in the risk of patient exposure to complications of OLV, further studies in different clinical and experimental settings are needed to evaluate the superiority of the ORi to SpO<sub>2</sub>.

## Key messages

- \* The oxygen reserve index (ORi™) (Masimo Corp., Irvine, CA, USA) is a novel pulse oximeter-based index which can detect the deterioration of blood oxygenation earlier than SpO<sub>2</sub>.
- \* Hypoxemia associated with one-lung ventilation (OLV) is possible incident in anesthesia.
- \* We verified the hypothesis that ORi declines earlier than SpO<sub>2</sub> by OLV and proved the hypothesis was correct [ORi vs. SpO<sub>2</sub>: 171 (102) vs. 372 (231) seconds to decline; P < 0.01].
- \* ORi has the possibility of contributing to earlier detection of hypoxemia due to OLV.

## Notes

### Details of the authors' contributions

W. K.: Patient recruitment, data collection and writing up of the first draft of the paper

M. K.: Study design, data analysis, patient recruitment and data collection

S. O.: Data collection

S. H.: Data collection

K. S.: Final approval of the version to be published

### Declaration of interests

The authors declare no conflict of interest associated with this manuscript.

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**Titles of tables and figures**

**Table 1.** Patient characteristics (n = 15).

**Table 2.** Respiratory data and complications of all patients

**Fig 1.** ORi can be assessed noninvasively by applying a sensor which is similar in form to a pulse oximeter sensor. This sensor uses multiwave length pulse co-oximetry. The picture is showing that ORi declines preceding a decline in SpO<sub>2</sub>. The picture was provided by Masimo Corp., Irvine, CA, USA.

**Fig 2.** The time courses for the changes in the oxygen reserve index (ORi) and percutaneous oxygen saturation (SpO<sub>2</sub>). 0 minutes = beginning of one-lung ventilation (OLV). Values are plotted 5 minutes before and every 30 seconds during OLV. Each plot and dotted line in red represent the median and the third quartile of ORi, respectively, while each plot and dotted line in blue represent the median and the first quartile of SpO<sub>2</sub> at each measurement point, respectively. +P < 0.01 vs. SpO<sub>2</sub>. The median values of ORi 5 minutes before and just before OLV were 0.3 [interquartile range (IQR) 0.25–0.38] and 0.29 [0.25–0.37], respectively. The median values of SpO<sub>2</sub> both of 5 minutes and just before OLV were 99 [99–100]%. The highest value of ORi after OLV was 0.31 [0.28–0.41]. It took 171 (102) seconds for the ORi to begin to decrease (the value at that time was 0.25 [0.21–0.35]), whereas it took 372 (231) seconds for SpO<sub>2</sub> to decrease by 1% (the value at that time was 98 [95–99]%).

**Fig 3.** The time courses for the changes in the PaO<sub>2</sub>, and PaCO<sub>2</sub>. 0 minutes = beginning of one-lung ventilation (OLV). Each plot and dotted line in orange represent the value of PaO<sub>2</sub>, while those in purple represent the value of PaCO<sub>2</sub>, respectively. Values are plotted 5 minutes before and every 3 minutes during OLV. The error bars stand for the interquartile range.

**Fig 4.** The time courses for the changes in the ORi, PaO<sub>2</sub>, and PaCO<sub>2</sub> in each patient. 0 minutes = beginning of one-lung ventilation (OLV). The line in red represent the value of ORi and values are plotted 5 minutes before and every 10 seconds during OLV. The rhombus and triangle in red on the line represent the highest value and starting point of declining of ORi. Each plot and dotted line in orange represent the value of PaO<sub>2</sub>, while those in purple represent the value of PaCO<sub>2</sub>, respectively. Values are plotted 5 minutes before and every 3 minutes during OLV. The down arrow in blue represent the starting point of declining of SpO<sub>2</sub>.

**Fig 5.** Plot of the oxygen reserve index (ORi) compared with arterial partial pressure of oxygen (PaO<sub>2</sub>) obtained from 15 patients during the study period. Linear regression analysis of ORi and PaO<sub>2</sub> shows a positive relationship ( $r^2 = 0.671$ ). The dotted lines indicate the 95% confidence interval of the regression line.

Table 1 Patient`s characteristics (n=15). Data are presented as mean (1SD).

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Age (yr)	61.0 (16.0)
Gender (male/female)	11/4
Weight (kg)	61.0 (7.0)
Height (cm)	161.5 (9.0)
Body mass index (kg/m <sup>2</sup> )	23.5 (3.7)

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Table 2 Respiratory data and complications of all patients

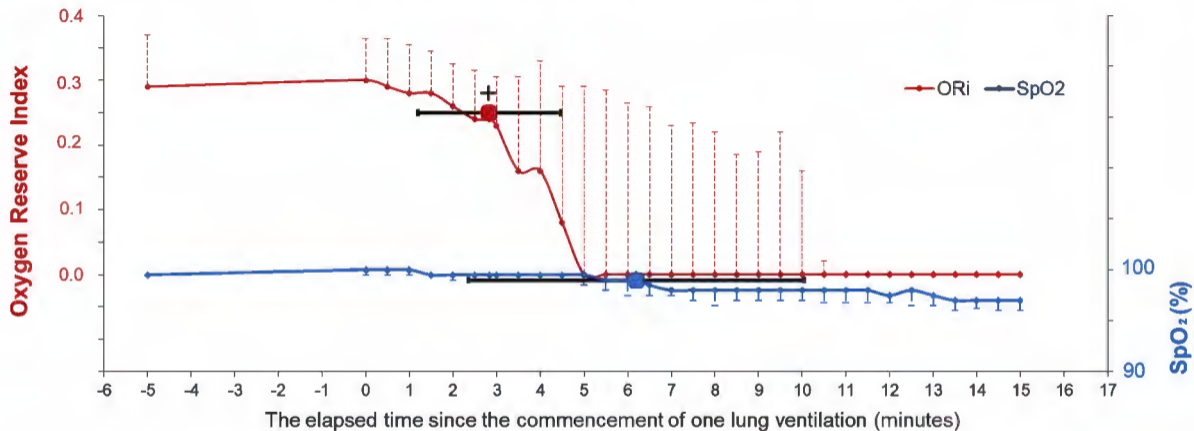
<b>Patient No.</b>	<b>FEV1% (%)</b>	<b>%VC (%)</b>	<b>Side of surgery (L/R)</b>	<b>Pathologies</b>	<b>Brinkman Index</b>	<b>Other respiratory complications</b>
<b>1</b>	78.9	91.8	R	Mucoepidermoid Carcinoma	0	asthma
<b>2</b>	73.1	80.1	R	Adenocarcinoma	0	-
<b>3**</b>	52.1	94.2	L	Metastasis of rectal cancer	900	-
<b>4</b>	86.3	96.8	R	Metastasis of urachal cancer	180	-
<b>5</b>	71.2	123.5	R	Adenocarcinoma	0	-
<b>6*</b>	60.0	127	L	Adenocarcinoma	60	
<b>7**</b>	67.2	92.0	L	Adenocarcinoma	1000	-
<b>8**</b>	64.1	131.2	L	Adenocarcinoma	1040	-
<b>9**</b>	66.5	132.0	L	Adenocarcinoma	840	-
<b>10</b>	77.5	130.7	R	Metastasis of malignant melanoma	0	-
<b>11+</b>	78.5	107.8	R	Adenocarcinoma	350	-
<b>12**</b>	69.5	112.1	R	Myxofibrosarcoma	940	-
<b>13+</b>	70.6	81.4	L	Squamous cell carcinoma	1520	radiation pneumonitis
<b>14</b>	78.2	96.8	R	Chest wall benign tumor	50	asthma
<b>15</b>	74.4	98.1	L	Metastasis of cervical cancer	230	-

The patients with \* have chronic obstructive pulmonary disease (COPD) defined as <70% of FEV1% and those with + are smoker patients defined as ≥300 of Brinkman Index.





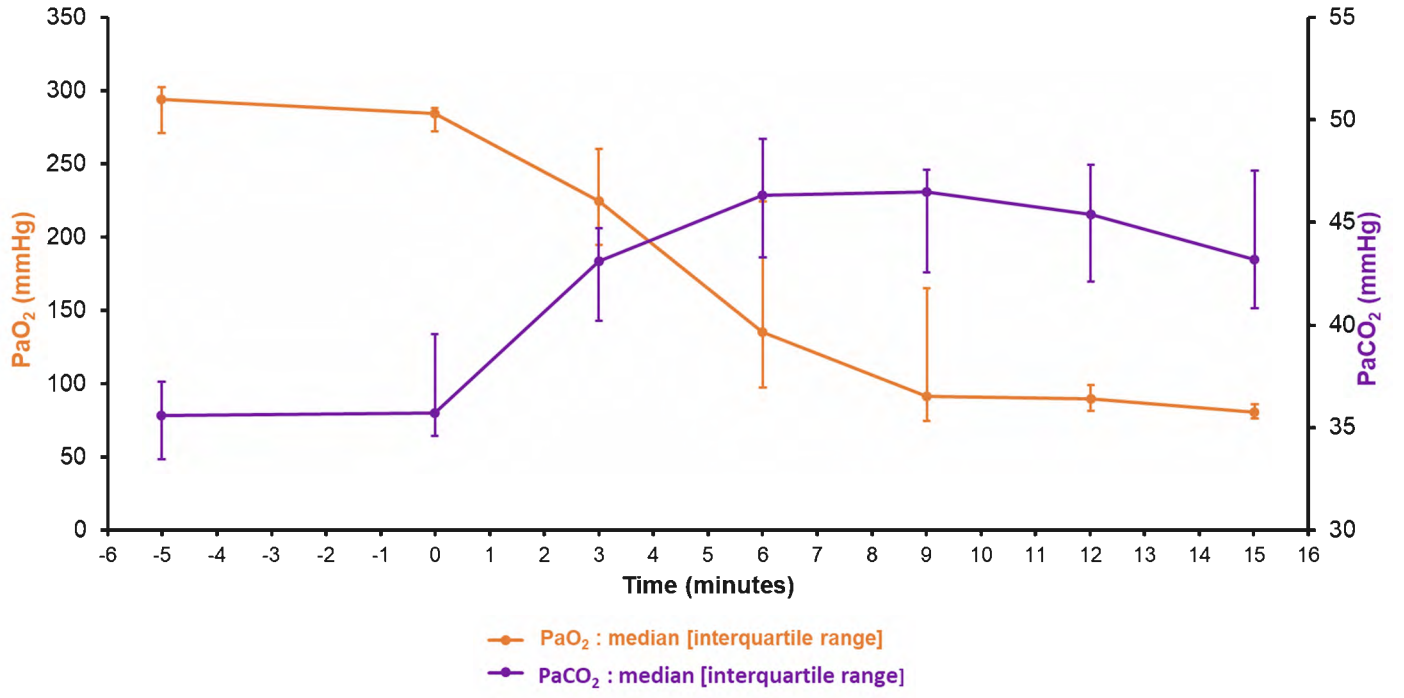
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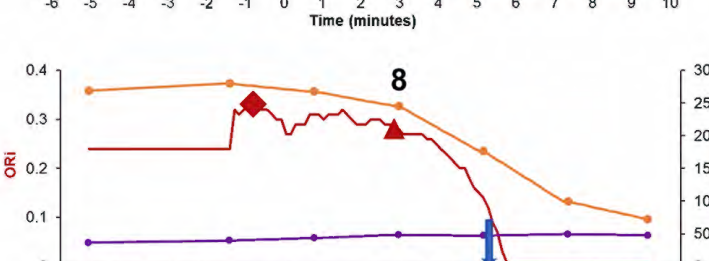
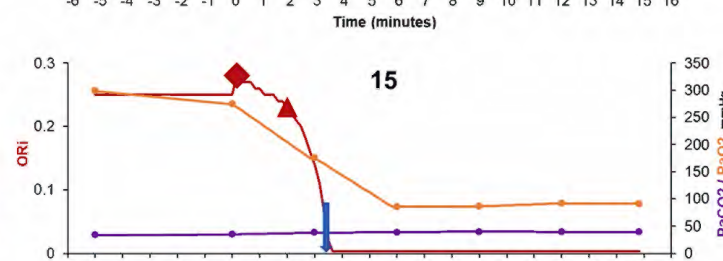
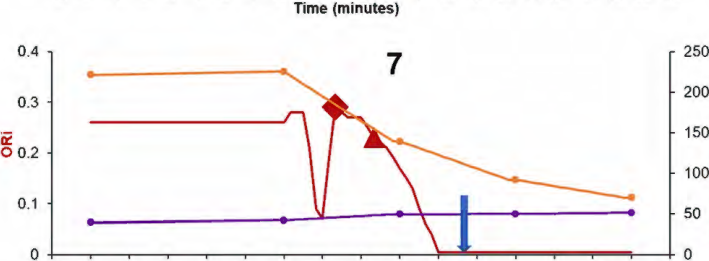
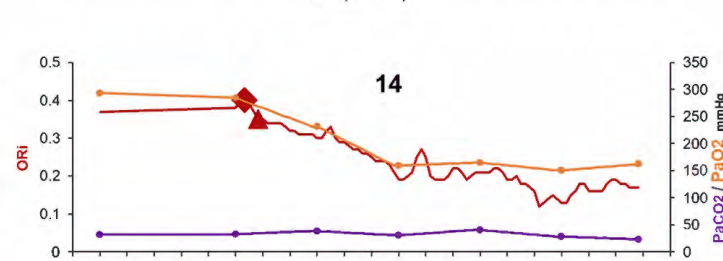
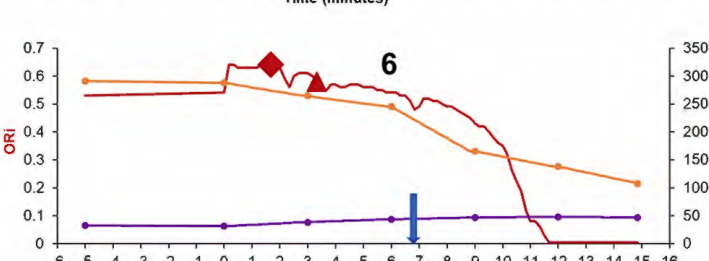
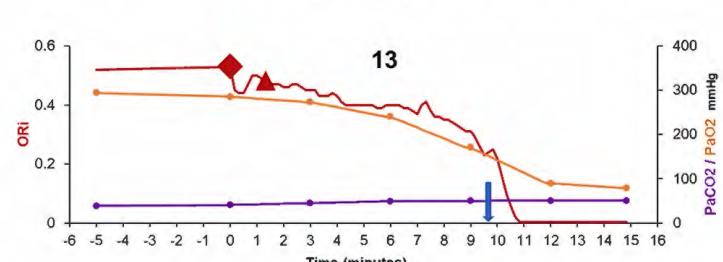
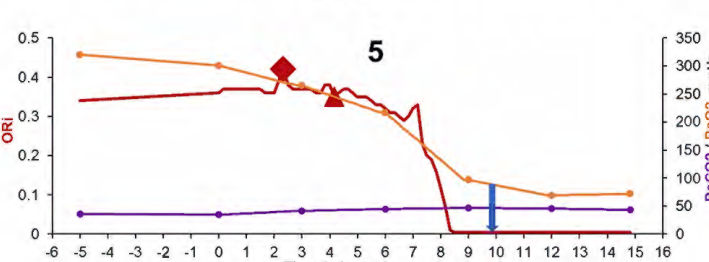
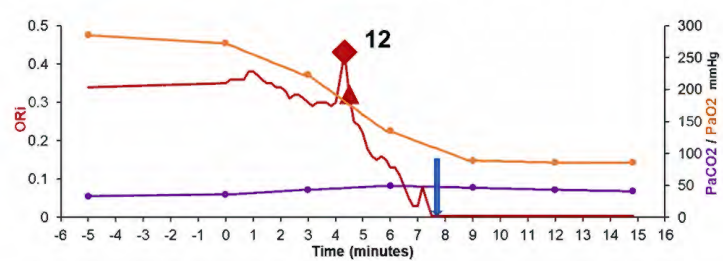
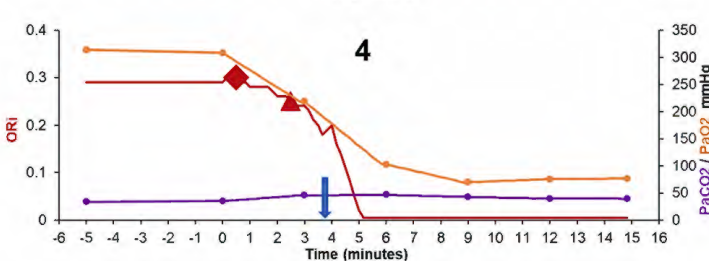
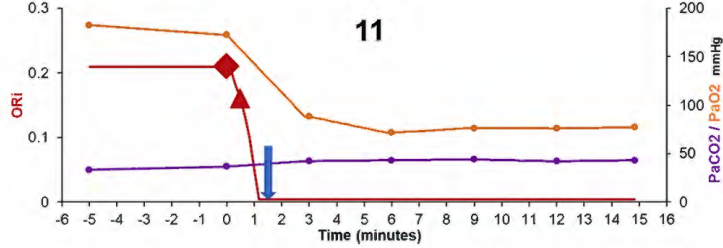
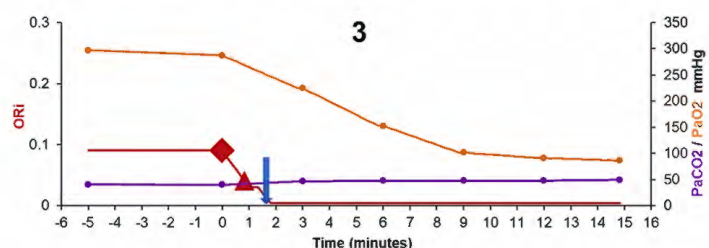
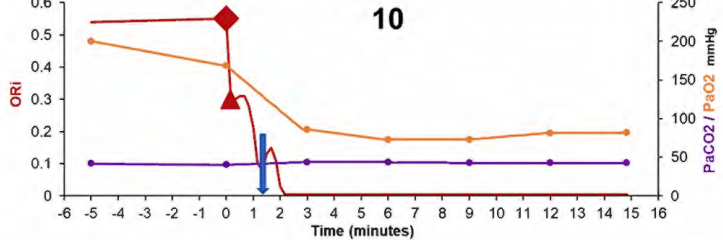
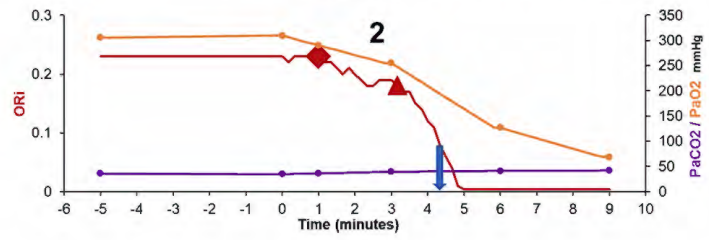
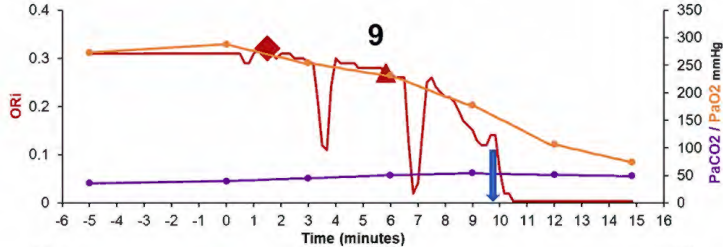
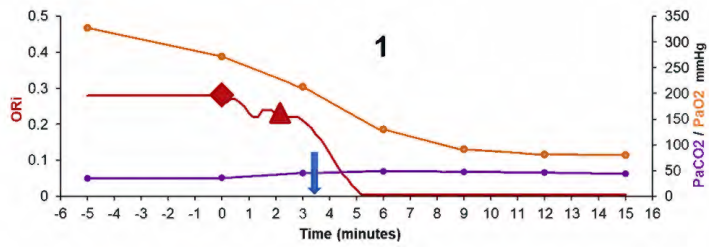


The point for ORI's beginning to decline  
The points and error bars represent mean (SD) values

The point for SpO2's beginning to decline  
The points and error bars represent mean (SD) values

The time courses for the changes in PaO<sub>2</sub> and PaCO<sub>2</sub>





Oxygen Reserve Index

