A comparison of the tissue oxygenation achieved using different oxygen delivery devices and flow rates

Denise F Blake, Philip Naidoo, Lawrence H Brown, Derelle Young and John Lippmann

Abstract

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Introduction: High-concentration normobaric oxygen (O_2) administration is the first-aid priority in treating divers with suspected decompression illness. The best O_2 delivery device and flow rate are yet to be determined.

Aim: To determine whether administering O_2 with a non-rebreather mask (NRB) at a flow rate of 10 or 15 L·min⁻¹ or with a demand valve with oronasal mask significantly affects the tissue partial pressure of O_2 ($P_{tc}O_2$) in healthy volunteer scuba divers.

Methods: Fifteen certified scuba divers had $P_{tc}O_2$ measured at six positions on the arm and leg. Measurements were taken with subjects lying supine whilst breathing O_2 from a NRB at 10 or 15 L·min⁻¹, a demand valve with an adult Tru-Fit oronasal mask and, as a reference standard, an oxygen 'head hood'. End-tidal carbon dioxide was also measured.

Results: While none of the emergency delivery devices performed as well as the head hood, limb tissue oxygenation was greatest when O_2 was delivered via the NRB at 15 L·min⁻¹. There were no clinically significant differences in end-tidal carbon dioxide regardless of the delivery device or flow rate.

Conclusion: Based on transcutaneous oximetry values, of the commonly available emergency O_2 delivery devices, the NRB at 15 L·min⁻¹ is the device and flow rate that deliver the most O_2 to body tissues and, therefore, should be considered as a first-line pre-hospital treatment in divers with suspected decompression illness.

Key words

Scuba diving; decompression illness; first aid; oxygen; equipment; transcutaneous oximetry; medical kits; DAN (Divers Alert Network)

Introduction

Scuba diving is a pastime enjoyed by many people around the world. Decompression sickness (DCS) and arterial gas embolism (AGE) are risks for divers, collectively termed decompression illness (DCI). The depth and time of the dive as well as the mixture of the breathing gas used by the diver are major factors affecting the amount of inert gas, such as nitrogen, absorbed. DCS is caused when this inert gas is released from solution in the form of bubbles that accumulate in body tissues, lymphatic ducts and blood vessels. AGE is typically the result of pulmonary barotrauma, but may also be released de novo in severe DCS. Inert gases are eliminated from the body through respiration, and breathing a high concentration of oxygen (O₂) increases the diffusion gradient for the inert gas between blood in the pulmonary capillaries and the alveoli, such that more gas moves into the alveoli to be exhaled. Oxygen should be given early to a diver with symptoms and signs of DCI, allowing them to better 'off gas' the excess inert gas and to supply more O, to hypoxic tissues.^{2–5}

The current first-aid and pre-hospital care recommendation is that O₂ be delivered at the highest possible concentration to divers with symptoms and signs of DCI.⁶ Divers Alert Network (DAN) America reports that the most commonly used O₂ delivery device for divers is the non-rebreather mask (NRB),³ although this might not be the case in other parts of the world. The recommended initial O₂ flow rate with the NRB mask for divers with suspected DCI has historically

been 15 L·min⁻¹.⁶ Recently, DAN America reduced its recommended flow rate to 10-15 L·min⁻¹, largely based on extending the duration of often limited O_2 supplies in the field, while still providing increased oxygenation.⁷ However, it is not known what effect, if any, this lower flow rate would have on tissue oxygenation.

This study used transcutaneous oximetry measurement (TCOM) to determine tissue oxygenation in subjects breathing O_2 via an NRB at both 15 and $10 \, \text{L} \cdot \text{min}^{-1}$ flow rates, as well as via a demand valve with an oronasal mask. TCOM is a non-invasive technique that uses heated electrodes on the skin to measure the partial pressure of tissue oxygen $(P_{\text{tc}}O_2)$. The primary null hypothesis was that there would be no difference in the $P_{\text{tc}}O_2$ achieved after 10 minutes of breathing O_2 with any of the devices or flow rates.

Methods

Ethics approval was granted from The Townsville Health Service District Human Research Ethics Committee (HREC12/QTHS/203). The participants were healthy, volunteer, certified scuba divers recruited from the students and staff at The Townsville Hospital and James Cook University in Townsville. Participants were at least 18 years of age and had performed at least one dive within the previous twelve months. Each was given a study information sheet and provided written, informed consent. Participants were asked not to smoke and to refrain from consuming food or caffeine or performing heavy exercise for

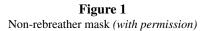




Figure 2
Demand valve (with permission)



two hours prior to participating in the study. Tidal volume (V_T) was measured using the EasyOne Spirometer (ndd Medical Technologies, Andover, MA, USA) according to the manufacturer's instructions. The participants were then placed in a supine position on a hospital stretcher with their head slightly raised on one pillow for the duration of the study. The room temperature was maintained at $22.0–22.5^{\circ}$ C; participants were offered a blanket for comfort and to limit any vasoconstrictive effects of being cold.

Baseline characteristics were documented, including age, gender, height, weight, O₂ saturation and blood pressure. A nasal cannula with an end-tidal carbon dioxide (ETCO₂) sensor (MAC-SAFETM nasal cannula, Vital Signs Inc., West Sussex, UK) was positioned and attached to a bedside monitor (GE Carescape Monitor B650, GE Healthcare Finland OY, Helsinki, Finland) via a water trap (GE Mini D-fendTM, GE Healthcare Finland OY, Helsinki, Finland).

Tissue oxygenation was measured using the TCM400 Transcutaneous Oxygen Monitoring System (Radiometer, Copenhagen, Denmark) with tc Sensor E5250. The $P_{\rm tc}O_2$ electrodes were calibrated using room air prior to each monitoring period, as per the manufacturer's recommendations. To compensate for the environmental relative humidity and barometric pressure, a 'humidity correction factor' calculated from the room temperature, saturated water vapour pressure and relative humidity was entered into the TCM machine. All TCOM assessments were performed by the same technician. The TCM400 displays $P_{\rm tc}O_2$ values in units of mmHg.

Six TCOM sensors were used, three on one leg and three on one arm. ^{9,10} The sensor sites were prepared by shaving hair if necessary, wiping clean, rubbing with an alcohol swab, and drying with gauze. One sensor was placed mid-way

between the highest bony point on the shoulder and the olecranon process on the lateral aspect of the upper arm. One sensor was five centimetres distal to the brachial crease on the lateral aspect of the lower arm, and one over the thenar eminence. One leg sensor was placed 10 cm distal to the lateral femoral epicondyle, one 5 cm proximal to the lateral malleolus and one on the dorsum of the foot between the first and second metatarsal heads attempting to avoid large, superficial vessels. The leads were secured in place with tape to minimize pull on the sensor. The participants rested quietly while the sensors were placed. They were requested to minimise talking during the study, but not allowed to sleep. The investigator remained in the room for the duration of the data collection.

Initial normobaric, room air readings from all sensors were recorded after a minimum 20 minute equilibration period that allowed all sensors to stabilize. The participants were then asked to breathe O_2 for 10 minutes using each of four different O_2 delivery methods:

- NRB mask (Figure 1; Topster SM-H051, Sturdy Industrial Co Ltd) at 10 L·min⁻¹;
- NRB mask at 15 L·min⁻¹;
- demand valve (Figure 2; L324-020, Allied Healthcare Products, St. Louis, MO, USA) with tight-fitting adult Tru-Fit oronasal mask;
- clear plastic 'head hood' and rubber neck dam (not shown) at 15 L·min⁻¹.

DAN has designed a variety of portable O_2 delivery units to provide divers with O_2 .^{6,7} These units have two common components: (1) a constant flow capability for use with a NRB mask or other constant-flow delivery device; and (2) a pressure-cycled demand valve. We therefore evaluated both the constant-flow and demand valve delivery mechanisms. In Australia, a TCOM assessment normally involves a 100%

normobaric O_2 challenge using a clear head hood with a neck seal at an O_2 flow rate of 15 L·min⁻¹. Therefore, we used the hood as our reference standard.^{9,10}

The order of the four $\rm O_2$ delivery devices was randomised. Sensor readings were recorded at the end of the 10-minute $\rm O_2$ breathing period, once stabilized. A pilot study confirmed that 10 minutes on $\rm O_2$ and 10 min between devices was adequate. After each 10-min $\rm O_2$ breathing period, participants breathed room air for 10 min, allowing all TCOM levels to return to baseline before the next device was trialled. Medical grade $\rm O_2$ was supplied from a wall outlet, or from a C-size cylinder for the demand valve. New NRB masks and ETCO₂ nasal cannulas were used for each participant.

The NRB masks were examined to ensure that the three one-way valves were in place, and then primed with O_2 to inflate the reservoir bag. The mask was positioned on the participant's face and adjusted to obtain the best possible seal. The participants were asked to breathe normally and the reservoir bag was monitored for collapse during the breathing periods. When breathing O_2 with the demand valve and oronasal mask, the participant was asked to breathe a little more deeply to trigger the valve. ¹²

ANALYSIS

The primary outcome of this study was a determination of the differences between $P_{tc}O_2$ readings in healthy volunteer divers breathing O_2 via a hood, through an NRB at 15 and $10 \, \text{L} \cdot \text{min}^{-1}$ and through a demand valve with oronasal mask. Based on previous research, we expected mean $P_{tc}O_2$ values between 300 mmHg (forearm) and 380 mmHg (upper arm), with a sample standard deviation of 68 mmHg, when subjects breathed $100\% \, O_2.^9$ Using the mid-point of that range (340 mmHg), assuming a decrease of 75 mmHg would be clinically significant, and allowing for substantial correlation (r = 0.90) between the repeated measures, a sample size of 13 subjects would provide a power of 80% (with $\alpha = 0.05$) to detect clinically significant changes in tissue oxygenation.

Because of the small sample size, none of the data were normally distributed (that is, the histograms were skewed) despite having similar medians and means, and generally narrow standard deviations. Thus, differences between median $P_{tc}O_2$ readings using the various delivery devices and flow rates were analysed using the Friedman Test, as were the ETCO $_2$ readings. Wilcoxon Sign Rank test with Bonferroni correction was used for post-hoc paired analyses.

Results

Fifteen healthy volunteers, five male and 10 female, met all of the inclusion criteria and completed the study protocol. Their demographic and baseline data, including interquartile range (IQR), are shown in Table 1. Baseline measures of perfusion were clinically unremarkable in all participants.

 Table 1

 Demographics and baseline characteristics of the 15 participants

| Characteristic | Median | (IQR) | Range | |
|------------------------------|--------|-----------|----------|--|
| Age (years) | 27 | (23-36) | 21-56 | |
| Heart rate (beats·min-1) | 62 | (57-71) | 50-76 | |
| Systolic BP (mmHg) | 120 | (112-128) | 109-133 | |
| Diastolic BP (mmHg) | 65 | (62-74) | 58-77 | |
| Respiratory rate | | | | |
| (breaths·min ⁻¹) | 15 | (12-18) | 10-20 | |
| Demand valve rate | | | | |
| (breaths·min ⁻¹) | 9 | (8-11) | 6–19 | |
| Oxygen saturation (%) | 99 | (98-100) | 97-100 | |
| Tidal volume (ml) | 700 | (620–790) | 500-1150 | |
| Number of scuba dives | 80 | (20–396) | 6-5000 | |
| Number of seuba dives | 80 | (20-390) | 0-3000 | |

Tables 2 and 3 display median IQR for the P_{tc}O₂ readings, the significance levels across all sensor sites, oxygen delivery devices and flow rates and a summary of the post hoc analysis across all the devices and sensor sites. As expected, P_tO₂ values were highest when subjects breathed near 100% O_2 wearing the head hood, with median $P_{t_2}O_2$ readings above 300 mmHg for all but the most distal sites. The NRB at 15 L·min⁻¹ achieved statistically better oxygenation than the NRB at 10 L·min⁻¹ and the demand valve at all sites, although the difference between the NRB at 15 L·min⁻¹ and the NRB at 10 L·min⁻¹ did not exceed our a priori clinically significant level (75 mmHg). The difference between the NRB at 15 L·min-1 and demand valve was also statistically significant (Table 2) and exceeded our threshold for clinical significance at all sensor sites. Oxygenation achieved with the NRB at 10 L·min⁻¹ was statistically similar to the oxygenation achieved with the demand valve, although the NRB at 10 L·min⁻¹ achieved clinically better oxygenation than the demand valve at all of the arm sensor sites.

 ${
m ETCO_2}$ was statistically higher when patients breathed ${
m O_2}$ using the NRB at $10~{
m L\cdot min^{-1}}$ compared to NRB at $15~{
m L\cdot min^{-1}}$ (Table 2), but the difference (approximately 1 mmHg) would not be clinically relevant, and there were no statistically significant differences between ${
m ETCO_2}$ levels among any of the other device comparisons.

Discussion

 $\rm O_2$ is the first-aid treatment of choice for divers suspected of having DCI.^{2,3,6,7,13,14} Oxygen has been shown to improve symptoms and decrease the number of hyperbaric treatments required.^{3,14} An understanding of the factors influencing the delivered $\rm O_2$ concentration from different devices is important in selecting first-aid $\rm O_2$ equipment.¹⁵ Near 100% $\rm O_2$ via a head hood performed the best of all the devices tested in this study but it is not practical for use in the field. Of the commonly available first-aid or pre-hospital $\rm O_2$ devices, the NRB at 15 L·min⁻¹ is the device and flow rate that achieves the highest level of tissue oxygenation.

Table 2

Transcutaneous oxygen partial pressures (mmHg) while breathing oxygen from different delivery devices (median and inter-quartile range shown); NRB – non-rebreather mask; L – litres; min – minute; NRB 10 – NRB at 10 L·min⁻¹; NRB 15 – NRB at 15 L·min⁻¹; ETCO₂ – end-tidal carbon dioxide; (*P*-values based on the Friedman test)

| | NRB | 3 10 L·min ⁻¹ | NRB | 3 15 L·min ⁻¹ | Den | nand valve | Не | ad hood | P-value |
|--------------------------|-----|--------------------------|-----|--------------------------|-----|------------|-----|------------|---------|
| Sensor 1 (upper arm) | 261 | (222, 301) | 307 | (269, 337) | 158 | (143, 244) | 396 | (358, 414) | 0.005 |
| Sensor 2 (lower arm) | 230 | (166, 260) | 255 | (199, 304) | 141 | (125, 164) | 346 | (314, 384) | 0.002 |
| Sensor 3 (palm hand) | 236 | (172, 264) | 264 | (212, 290) | 169 | (111, 219) | 328 | (279, 357) | < 0.001 |
| Sensor 4 (lateral leg) | 182 | (145, 205) | 215 | (175, 259) | 100 | (77, 187) | 300 | (260, 338) | < 0.001 |
| Sensor 5 (lateral ankle) | 142 | (126, 184) | 202 | (142, 237) | 91 | (73, 147) | 264 | (192, 342) | < 0.001 |
| Sensor 6 (dorsum foot) | 97 | (61, 177) | 152 | (82, 208) | 63 | (44, 151) | 163 | (136, 287) | < 0.001 |
| ETCO ₂ | 33 | (32, 35) | 32 | (30, 33) | 34 | (28, 36) | 32 | (31, 33) | 0.002 |

Table 3

Statistically significant difference in $P_{tc}O_2$ post-hoc comparisons using Wilcoxon Sign Rank test with Bonferroni correction; P < 0.05 considered significant; NRB – non-rebreather; NRB 10 – NRB at 10 L·min⁻¹; NRB 15 – NRB at 15 L·min⁻¹;

Head hood > NRB 10 Head hood > NRB 15 Head hood > Demand valve NRB 15 > NRB 10 NRB 15 > Demand valve NRB 10 = Demand valve (for all sensor sites)

Often, desirable dive sites are far from shore or in remote areas where hospital care, let alone hyperbaric therapy, is not immediately available. The demand valve only delivers O_2 when the diver inspires and, therefore, allows for conservation of O_2 – dependent on the tidal volume of the user. The ease of use, familiarity for divers, potential to deliver high inspired O_2 concentrations 16 as well as the potential for O_2 -supply conservation has led to the recommendation of the demand valve as the O_2 delivery method of choice in the first-aid and pre-hospital treatment of DCI. 13 Lower O_2 flow rates with the NRB have been suggested to conserve O_2 . However, our study demonstrates lower tissue O_2 levels with both these approaches, questioning the clinical efficacy of these recommendations.

Typically, first-aid oxygen units, such as that marketed by the Divers Alert Network, use a relatively small-sized O_2 cylinder, containing around 490 (Australian C-size cylinder) to 635 litres (US Jumbo D-size cylinder) of oxygen.⁶ This finite supply of O_2 is designed to treat the diver for a short time on scene while transporting them back to shore and/or arranging ambulance or air-medical transport.^{7,13} At a 15 L·min⁻¹ flow rate, the 490 litre C-size cylinder would last for just over 30 minutes and at 10 L·min^{-1} approximately 45 minutes.¹⁷ This is the disadvantage of using an open system.¹⁸ In our study, participants breathing O_2 via the demand valve had a lower median respiratory rate of nine breaths per minute. Thus a C-sized cylinder used with a

demand valve might last longer than 45 minutes, but with lower levels of tissue oxygenation. Whether higher tissue $\rm O_2$ levels for a shorter time period are clinically better than lower tissue oxygenation for a longer period of time in reducing symptoms and signs of DCI remains to be determined through clinical studies.¹⁹

The findings for the demand valve were unexpected and counter-intuitive; we anticipated $P_{tc}O_2$ readings with the demand valve to approach or exceed those with an NRB at 15 L·min⁻¹. The findings are consistent with earlier findings in a hyperbaric chamber that breathing O_2 via a demand valve achieved adequate inspired O_2 concentrations (F_1O_2) only when coached by trained staff.²⁰ Other investigators have explored semi-closed-circuit O_2 delivery devices for the delivery of O_2 in DCI.^{17,18} None of these devices, however, are commonly used by recreational divers, partly due to increased complexity and training and maintenance requirements.

A potential limitation to our study is that we did not measure the arterial oxygen partial pressure $(P_a O_2)$ but, rather, used $P_{\rm tc} O_2$ as a non-invasive method of measuring tissue oxygenation. Many DCI symptoms are caused by tissue nitrogen bubbles, therefore a measurement estimating tissue oxygenation may be more relevant for this study. Further, any bias associated with using $P_{\rm tc} O_2$ instead of $P_a O_2$ would be a non-differential bias, consistent across all participants and all devices and would not affect the relative within-subject differences in oxygenation achieved by each device.

We measured F_1O_2 directly via the nasal cannula whilst subjects used the hood. With this apparatus, F_1O_2 levels reached 98% in approximately 6 min. Since $P_{tc}O_2$ levels using the NRB and demand valve were both clinically and statistically less than those obtained while breathing O_2 in a hood, we can confidently say that no first-aid or pre-hospital device provided 100% inspired O_2 . However, we remain of the opinion that the gold standard for oxygen administration in first aid for DCI is an F_1O_2 of 100%. This should be achievable using the DAN demand valve, but further work is needed on methods of deploying the demand valve in order to ensure it delivers this F_1O_2 .

It is important that NRB masks are in good condition (i.e., not distorted) with all three one-way valves fitted and that a reasonable face seal is achieved. This is too often not the reality in the diving community. In our study, the ETCO₂ nasal cannula tubing may have contributed to a compromised mask seal, although we attempted to keep this to a minimum.

We used a single, new demand valve in this study. We did not test the inhalation and exhalation resistances of this valve. If the inhalation resistance was higher than specified by the manufacturer, air may have been entrained via an antiasphyxia function reducing the inspired O, concentration. This is more of a problem when a diver is sitting with their head down or lying on their side. 13 Two subjects were noted to have red marks on their face after breathing from the demand valve. When questioned about this, they stated that they knew they had to hold the mask tightly to decrease the amount of air entrained. However, these two participants did not have higher demand valve P_{to}O₂ levels than other participants. It may be beneficial to educate first aid providers and divers to ensure the diver holds the demand valve mask tightly to their face and breathes sufficiently deeply to trigger the valve. Anecdotally, the subjects felt the demand valve was the most uncomfortable to use.

Conclusion

Based on $P_{tc}O_2$ values, of the commonly available first-aid O_2 delivery devices, the NRB at 15 L·min⁻¹ is the device and flow rate that delivers the most O_2 to body tissues and, therefore, should be considered as a first-line treatment in divers with suspected DCI.

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Conflict of interest

John Lippmann is the Chairman and Director of Research, DAN Asia-Pacific, which sells oxygen equipment.

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Denise F Blake^{1,2}, Philip Naidoo¹, Lawrence H Brown³, Derelle Young⁴, John Lippmann⁵

- ¹ Emergency Department, The Townsville Hospital, Townsville, Queensland, Australia
- ² College of Marine and Environmental Sciences, James Cook University, Townsville
- ³ Mount Isa Centre for Rural and Remote Health, James Cook University, Townsville
- ⁴ Hyperbaric Medicine Unit, The Townsville Hospital, Townsville
 ⁵ Divers Alert Network Asia-Pacific, Melbourne, Victoria, Australia

Address for correspondence:

Denise F Blake

Emergency Department, The Townsville Hospital Townsville, Queensland, Australia 4814 **E-mail:** <denise.blake@health.qld.gov.au>