Oxygen Delivery With an Open Oxygen Mask and Other Conventional Masks: A Simulation-Based Study

Morgan E Sorg and Robert L Chatburn

BACKGROUND: A recently introduced open oxygen mask design was marketed in 2021 (open mask A). The manufacturer claims that the mask "...provides one solution for all your oxygen delivery needs across your patients' continuum of care." The new oxygen mask specifies flow (1–15 L/min and flush) with an expected F_{IO_2} from 0.25–0.85. This suggests that this mask eliminates the need for multiple oxygen delivery devices as F_{IO_2} requirements change. This study aimed to describe the F_{IO_2} performance of the new open oxygen mask and other commonly used oxygen masks. METHODS: The following oxygen masks were studied: open mask A, open mask B, simple mask, partial rebreather, and non-rebreather. An adult mannequin head was attached to a breathing simulator, which recorded F_{IO_2} at the simulated alveolar level. The simulator was set to a closed-loop volume control mode: V_T = 320 mL, compliance = 50 mL/cm H_2O, resistance = 4 cm H_2O/L/s, breathing frequency = 15 breaths/min, increase = 25%, hold = 0%, and release = 30%. Oxygen was run through each mask at the recommended flows. Each flow was verified with a flow analyzer before attaching the mask for oxygen measurement. Each experiment was performed twice. The F_{IO_2} measurements were averaged and compared using a 2-way ANOVA with $P < .05$ indicating significance. RESULTS: The F_{IO_2} delivery was significantly different for each device. The measured F_{IO_2} range was open mask A, 0.30–0.60; open mask B, 0.28–0.64; simple mask, 0.55–0.73; partial non-rebreather, 0.73–1.0; non-rebreather, 0.93–1.00. CONCLUSIONS: The performance of each oxygen mask from highest to lowest F_{IO_2}: non-rebreather, partial rebreather, simple mask, open mask A, and open mask B. These findings suggest that no oxygen mask tested serves as a substitute for the others across a flow range of 1–15 L/min and flush. *Key words: oxygen therapy; oxygen mask; lung simulator; open mask.* [Respir Care 2022;67(3):316–321. © 2022 Daedalus Enterprises]

Introduction

Oxygen therapy administration is used frequently in the care of acutely and chronically ill patients presenting with hypoxemia. To meet a patient's oxygen requirements, there are different devices available to deliver a range of F_{IO_2} (Table 1).[1-4] The clinician must understand the capabilities and limitations of each system to select the most appropriate oxygen device.[1] Oxygen systems designed to allow adjustment of oxygen source flow are considered variable performance devices because the device only provides some of the inspired gas required to meet the patient's inspiratory demands. The amount of oxygen the patient receives is highly dependent on the amount of room air the patient inhales compared to that inhaled from the device.[1] Specifically, F_{IO_2} is defined as the volume of oxygen inhaled as a fraction of the total inhaled volume. To the extent that inspiratory flow exceeds the constant flow of the device, the F_{IO_2} will be reduced.

Oxygen systems designed to allow adjustment of F_{IO_2} (by changing air entrainment ratios) are considered fixed performance because the amount of oxygen delivered is more independent of the inspiratory flow.[5,6] Partial rebreather and non-rebreather oxygen masks provide neither adjustment of inspired oxygen flow nor entrainment. The advantage of these masks is that the source flow need not be greater than the patient's inspiratory flow because the bag

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Mr Chatburn has disclosed relationships with IngMar Medical, Vyaire Medical, Inovytec, Temple, Aires, Ventis Medical, and ProMedic Consulting. The other author has disclosed no conflicts of interest.

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Table 1. Oxygen Delivery Devices and Expected F_{IO_2} Delivery at Flow Range

Device Type	Device	Suggested Flow Range (L/min)	Expected F_{IO_2}
Adjustable	Nasal cannula	1–6	0.22–0.40
Oxygen	Simple mask	5–10	0.35–0.50
Source Flow	Open mask A	1-Flush	0.25–0.85
	Open mask B	1-Flush	0.24–0.90
Adjustable F_{IO_2}	Entrainment mask	2–15	0.24–0.60
Non-adjustable	Partial rebreather	≥ 10	0.40–0.70
F_{IO_2}	Non-rebreather	≥ 10	0.60–0.80

provides a reservoir. Therefore, ideally, with source gas flow high enough to keep the bag inflated during inspiration, and zero leaks around the mask, and perfectly functioning valves, the F_{IO_2} should be close to 1.00.[7]

In 2001, the variable oxygen delivery device called the OxyArm (Southmedic, Barrie, Ontario, Canada) was developed.[6,8] The design of the OxyArm looks like the prongs of a nasal cannula that are attached to a hands-free telephone headset.[6] This device was designed to act as a diffuser to create a plume of oxygen directed toward the mouth and nose of the patient.[6] In 2005, an open-concept oxygen delivery mask, open mask B (OxyMask, Southmedic), was developed using a similar diffuser design as the OxyArm (Fig. 1).[6,9] Open mask B is an adjustable oxygen flow device with variable F_{IO_2} delivery, and the Southmedic web site states that "Respiratory mechanics and breathing patterns determine how room air combines with the delivered oxygen." The flow can be adjusted from 1–15 L/min and flush. The actual flow required should be determined by oxygenation effect using a pulse oximeter (https://southmedic.com/consumer-medical-products/medical-products/oxygen-delivery, *Accessed September 14, 2021*.). This open mask design has caught the attention of researchers because of its ability to reduce chances of CO_2 rebreathing.[10-12] Open mask B claims to deliver a range of F_{IO_2} (when measured at the lips) from 0.24–0.90. However, findings suggest that the F_{IO_2} delivery measured at the oropharynx is < the F_{IO_2} measured at the lips.[13]

A new open oxygen mask, open mask A (AirLife Open, Vyaire, Chicago, Illinois), was created in 2021 (Fig. 1). The design of open mask A is similar to the open-concept oxygen delivery mask design of open mask B.[13] Open mask A comes in 3 sizes: small (pediatric), medium (adult), and large (adult). The manufacturer states this mask "...provides one solution for all your oxygen delivery needs across your patients' continuum of care, instead of requiring multiple devices for changing flow needs." (https://www.vyaire.com/products/airlife-open, *Accessed September 14, 2021*.). For open mask A, the F_{IO_2} delivery (stated in the package insert) ranges from 0.25–0.85. This suggests that it could replace anything from a nasal cannula to a non-rebreather mask (Table 1). For example, from 1–3 L/min, the manufacturer suggests the F_{IO_2} delivery will be between 0.25–0.33; for 4–6 L/min, the specified F_{IO_2} should fall between 0.37–0.45, and so forth.

QUICK LOOK

Current knowledge

Oxygen therapy is used frequently in a variety of settings for patients with acute or chronic hypoxia. Studies have demonstrated that the F_{IO_2} delivered by different oxygen mask systems may vary depending on the oxygen flow and the patient's inspiratory flow.

What this paper contributes to our knowledge

This study confirms that F_{IO_2} delivery differed significantly among flow-adjustable oxygen mask devices. The measured F_{IO_2} for each device varied from the expected F_{IO_2} per the literature and manufacturers. F_{IO_2} delivery (highest to lowest) was as follows: non-rebreather, partial rebreather, simple mask, open mask A, open mask B.

The purpose of this simulation-based study was to describe the F_{IO_2} delivery performance of open oxygen masks and other commonly used oxygen masks across a range of flows.

Methods

Oxygen Delivery Devices

This study was created to describe the performance of 5 oxygen delivery devices. Each device is designed differently and poses the potential of CO_2 rebreathing if not used at the suggested flow. Table 1 lists the suggested flow range for each device and the expected F_{IO_2}.[1-4] The following adult oxygen masks were tested (Fig. 1): medium-sized open mask A (Vyaire Medical), open mask B (Southmedic), simple mask (Vyaire), partial rebreather (Vyaire), and non-rebreather (Vyaire). A medium-sized open mask A was selected as it was similar in size to the other masks being tested. As seen in Figure 1, the partial rebreather was used with a one-way valve in-line with the orifice to the bag but no valves placed on the openings on each side of the mask. The non-rebreather had 3 one-way valves: 2 on the mask and one to the bag (Fig. 1).

An adult mannequin head with an open-mouth and open-nares design (Michigan Instruments, Kentwood, Michigan) was attached to a breathing simulator (ASL 5000, software version 3.6, IngMar Medical, Pittsburgh, Pennsylvania), which is capable of measuring breath-by-breath F_{IO_2}. Before starting the experiment, the lung simulator oxygen sensor was calibrated per the manufacturer's instructions. Each mask was taped to the mannequin head to eliminate leaks.

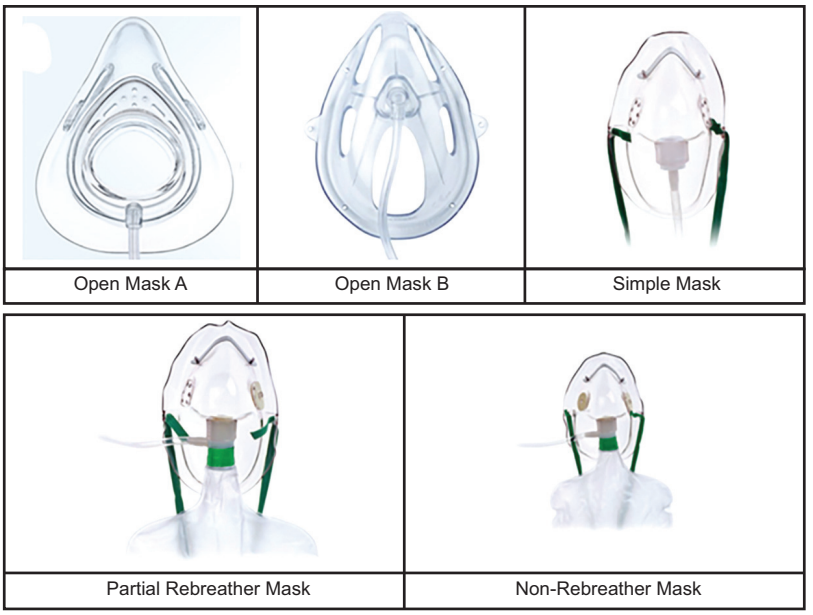

Fig. 1. Experimental oxygen delivery devices.

Table 2. Open Mask Selection Based on Assumed Patient Height

Mask Size	Patient Height
Small	3'9" (1.14 m)–5'5" (1.65 m)
Medium	4'11" (1.50 m)–6'9" (2.06 m)
Large	6'5" (1.96 m)–7'3" (2.21 m)

Lung Models

The breathing simulator was programmed to represent a normal adult lung. The simulation comprised a lung model (resistance and compliance) and an effort model (muscle pressure waveform). The parameters used to create a normal lung model were determined by applying evidence-based values.[14-17] Resistance was determined by subtracting the calculated resistance of an endotracheal tube, as described by Wilson et al,[15] from the airway resistance of an intubated subject as published by Arnal et al.[14] This resulted in a simulated, normal, non-intubated resistance of 4 cm H_2O/L/s. A compliance of 50 mL/cm H_2O was used to represent normal lungs.[14] The breath frequency was calculated based on an average respiratory rate of an adult, f = 15 breaths/min.[17] The effort model had the parameters for a maximum muscle pressure (P_{max}), % increase in muscle pressure during inspiration, and d percentage release during expiration. In a normal breathing model, the expiratory phase is passive. Data from Gallagher et al[16] helped to determine the simulation parameters: increase = 25%, hold = 0%, release = 30%. P_{max} was automatically adjusted by the breathing simulator to achieve the target V_T set.

The breathing simulator was set to closed-loop volume control (automatic adjustment of P_{max}) mode to achieve a target tidal volume (V_T) of 320 mL, regardless of the resistance offered by the mask. The V_T was calculated using Vyaire's suggestion for open mask A size selection based on assumed patient height (Table 2). The V_T selected fell within 6–8 mL/kg for a male patient with a height of 150 cm.

The main outcome variable of this study was F_{IO_2}. A medical flow meter was attached to a 50 psi oxygen gas source (medical-grade compressed oxygen H cylinder). Each flow setting was first verified with a Citrex H4 flow analyzer before attaching the oxygen mask to the flow meter (Fig. 2). Once the oxygen mask was attached to the flow meter and the oxygen reading was stable (~ 2 min), measured F_{IO_2} was recorded. Between each experiment, the oxygen source was shut off and the breathing simulator continued to run (breathing room air) until the F_{IO_2} reading was below 22%. Each device was tested twice at each flow setting.

Data Analysis

The mean and SD were calculated for each oxygen mask at each flow setting. The performance of each oxygen device was graphed across the flow range. The mean values for F_{IO_2} were compared across the flow range using a 2-way ANOVA. The measured F_{IO_2} range of each device was also graphically compared to the expected F_{IO_2} range based on the literature and/or manufacturer.

Results

Main results are shown in Table 3 and Figure 3.[1] The different devices resulted in different ranges of F_{IO_2} ($P <$

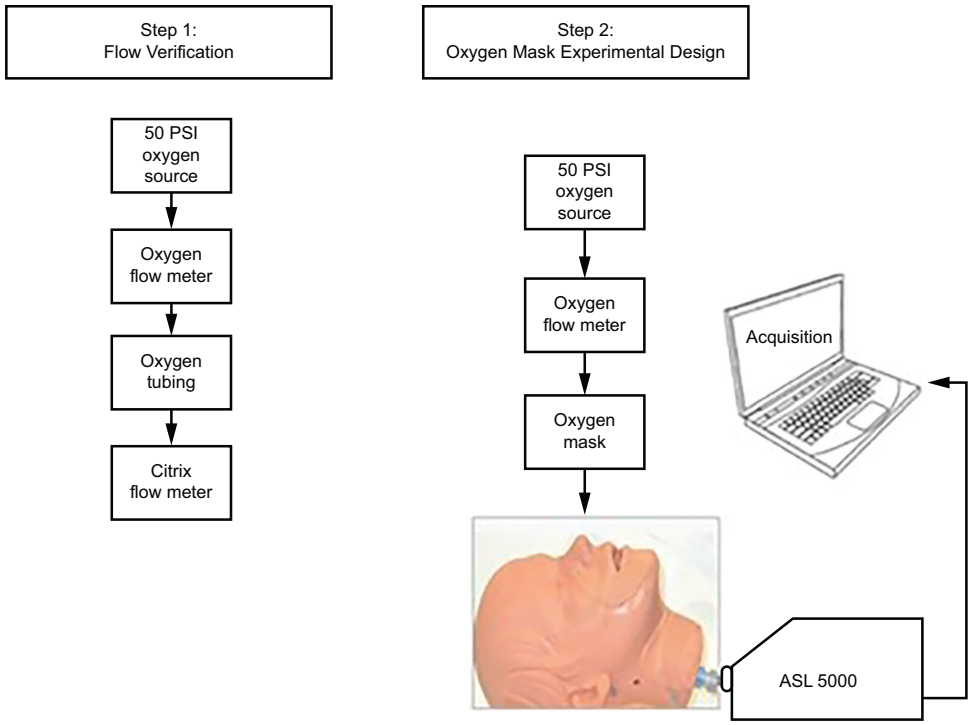

Fig. 2. Experimental set-up.

Table 3. Average Oxygen Delivery for Each Oxygen Mask F_{IO_2}

Flow (L/min)	Open Mask A		Open Mask B		Simple Mask		Partial Rebreather		Non-Rebreather	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
1	30	0.49	28	0.21						
2	36	0.28	31	0.57						
3	40	0.21	32	0.64						
4	43	0.57	36	0.21						
5	44	0.64	39	0.42	55	0.14				
6	47	0.64	40	0.21	59	0.57				
7	49	0	41	0	62	0.42				
8	50	0.21	42	0.07	65	0.21				
9	51	0.42	44	0.14	70	0.14				
10	52	0.42	45	0.21	73	0.07	73	0.07	93	0.28
11	53	0.49	47	0.71			76	0.71	94	0.21
12	55	0.28	48	0.71			79	0.28	95	0.64
13	55	0.14	50	0.71			82	0.14	96	0.64
14	57	0	51	0.28			84	0.35	97	0.71
15	59	0	52	0.99			86	0.14	98	0.92
Flush	65	0	64	0.71			100	0	100	0

.001). The ranking of these ranges was as follows (highest to lowest): non-rebreather, partial non-rebreather, simple mask, open mask A, and open mask B. For the open mask A and open mask B, measured F_{IO_2} fell within the lower end of the expected F_{IO_2} range (Fig. 4). The F_{IO_2} measured from the open mask A and open mask B set to flush was < the expected value (20% for open mask A and 26% for open mask B). The measured F_{IO_2} for the non-rebreather, partial rebreather, and the simple mask was all above the expected F_{IO_2} range (Fig. 4).

Discussion

In this simulation-based study, the performance of different oxygen masks was assessed. The open oxygen mask designs, open mask A and open mask B, provided

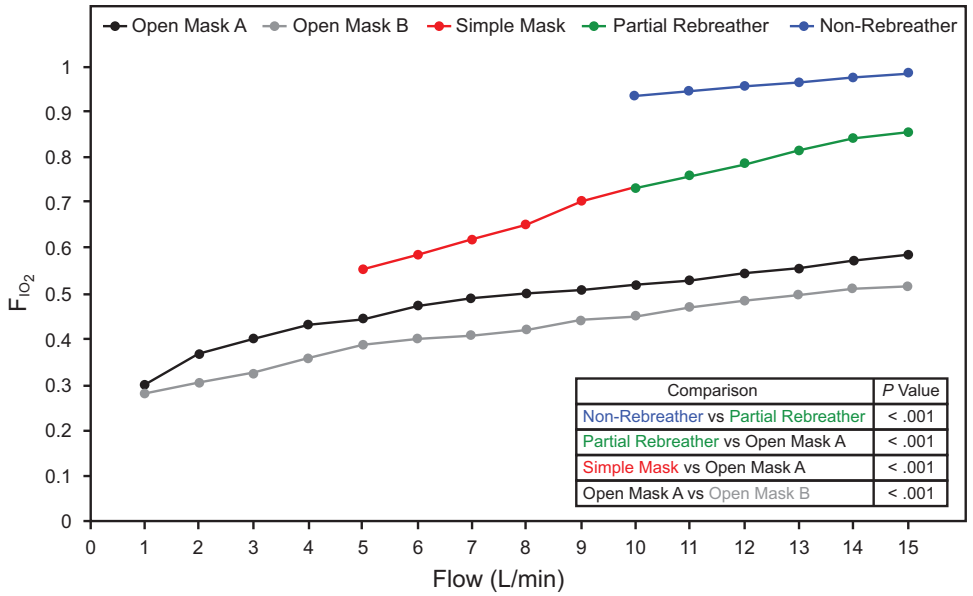

Fig. 3. Mask performance at each flow setting.

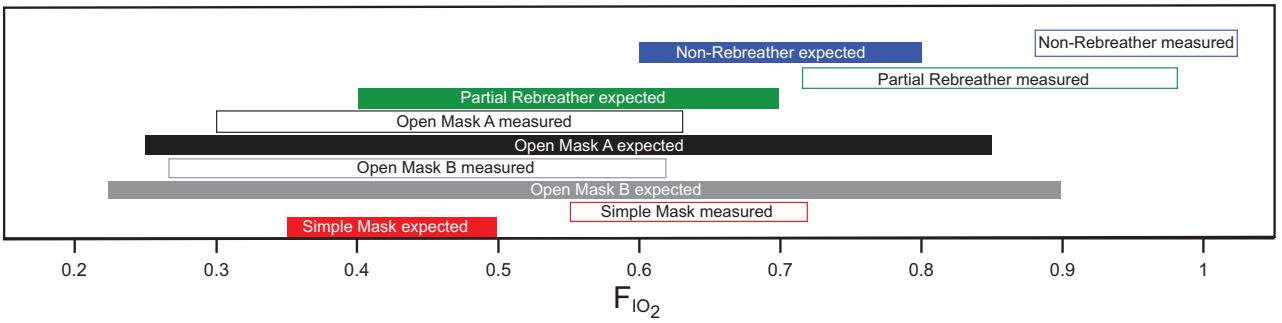

Fig. 4. Range of F_{IO_2} expected and measured.

significantly less F_{IO_2} ($P < .001$) compared to the non-rebreather, partial rebreather, and a simple mask. The measured F_{IO_2} range for the open mask A and open mask B was smaller than the expected F_{IO_2} range per the manufacturers (Fig. 4). The non-rebreather, partial rebreather, and a simple mask all provided a higher F_{IO_2} than expected, possible because all masks were taped to the mannequin face to prevent leaks, which reduced entrainment of room air compared to clinical use. These findings suggest that none of the masks can serve as a substitute for all oxygen masks across a range of required F_{IO_2}.

In observing the performance of the two open mask designs, the open mask A provided significantly higher F_{IO_2} than the open mask B at the same flow. On average, the difference in F_{IO_2} was about 0.06, which might not be clinically important. This study was not intended to explain why open mask A outperformed open mask B. We speculate that it is due to differences in their designs. Subsequent research is required to address these findings. If clinical application of an adjustable-flow oxygen device is titrated using S_{pO_2} or P_{aO_2}, the open mask A and open mask B may require higher flow(s) to provide similar F_{IO_2} compared to closed mask designs, eg, simple mask. However, using a simple mask may increase the risk of CO_2 rebreathing if a caregiver were to titrate the flow below 5 L/min. Failure to adjust flow correctly (within the suggested ranges) of conventional oxygen masks has resulted in "safety occurrences" with unknown patient effects.[12] Lamb and Piper demonstrated the ability of open mask B to decrease the chances of CO_2 rebreathing compared to a non-rebreather mask.[10] The use of this open-mask design has been shown to reduce the number of reported "safety occurrences."[12] The implementation of open mask B in one hospital was more cost effective because it decreased need to change between different oxygen devices as a patient's oxygen requirements changed.[12] Subsequent research is required to determine if open mask A prevents CO_2 rebreathing compared to other oxygen masks.

A major limitation of this study was that it was a simulation and was intended to describe the oxygen delivery of devices with one realistic simulated breathing pattern and was not intended to predict clinical performance. We used one set of simulation parameters and one sample of each type of oxygen mask. The mannequin head was not designed to replicate real human anatomy as other studies have done.[18] We do not know how this may impact results (eg, the effect of simulated dead-space volume). Experiments with other mannequin head designs may yield different results. As noted in the Introduction, if F_{IO_2} is not directly adjustable, then the performance of the device is dependent on a patient's inspiratory flow.[19,20] As mentioned earlier, the location of F_{IO_2} measurement (lips vs oropharynx vs alveoli) may also alter results.[13] Actual clinical performance of these masks would be best described by in vivo experiments.[13] The strength of this study was that we used a high-fidelity, actively breathing lung simulator with evidence-based parameters.

Conclusions

This study confirms that F_{IO_2} delivery differs significantly among flow-adjustable oxygen mask devices. Furthermore, the measured F_{IO_2} of all oxygen masks varied from their expected performance. In-depth knowledge of the oxygen delivery capabilities of each mask will help a clinician in selecting an appropriate mask to meet their patient's oxygen requirements. These findings suggest that for an adjustable-flow oxygen mask there is not one mask that can supply the full range of F_{IO_2} delivery. This study reiterates that after selecting the most appropriate device oxygen flow to the device is best titrated using S_{pO_2} or blood gas measurements.

REFERENCES

1. Heuer A. Medical gas therapy. In: Kacmarek RM, Stosser JK, Heuer AJ, editors. Egans Fundamentals of Respiratory Care, 11th edition. St. Louis, MO: Elsevier; 2017:905-936.
2. Lewarski J, Volsko T. Administering medical gases. In: Volsko TA, Chatburn RL, El-Khatib MF. Equipment for Respiratory Care. Burlington, MA: Jones & Bartlett Learning; 2016:33-60.
3. Vyaire Medical Inc. AirLife open brochure. 2020. Available at: https://www.vyaire.com/sites/us/files/2021-05/vyr-gbl-1900170-2.0-airlife-open-technical-data-sheet_vyaire-only_final.pdf. *Accessed May 18, 2021.*
4. Southmedic Inc. OxyMask oxygen therapy brochure. 2018. Available at: https://southmedic.com/wp-content/uploads/2020/03/OxyMask-wLR.pdf. *Accessed May 18, 2021.*
5. Hill SL, Barnes PK, Hollway T, Tennant R. Fixed performance oxygen masks: an evaluation. Br Med J (Clin Res Ed) 1984;288(6426):1261-1263.
6. Paul JE, Hangan H, Hajgato J. The OxyMask development and performance in healthy volunteers. Med Devices (Auckl) 2008;2:9-17.
7. Batool S, Garg R. Appropriate use of oxygen delivery devices. Open Anesthesiol J 2017;11(1):35-38.
8. Southmedic Inc. OxyArm brochure. 2018. Available at: https://southmedic.com/wp-content/uploads/2021/05/OxyArm-Sell-Sheet-1.pdf. *Accessed September 14, 2021.*
9. Beecroft JM, Hanly PJ. Comparison of the OxyMask and Venturi mask in the delivery of supplemental oxygen: pilot study in oxygen-dependent patients. Can Respir J 2006;13(5):247-252.
10. Lamb K, Piper D. Southmedic OxyMask compared with the Hudson RCI non-rebreather mask: safety and performance comparison. Can J Respir Ther 2016;52(1):13-15.
11. Ogiwara S, Tamura T, Sai S, Nojima M, Kawana S. Superiority of OxyMask with less carbon dioxide rebreathing in children. Eur J Pediatr 2021 Jun;180(12):3593-3597.
12. DeJuilio P, Jenkins M, Huml J. Evaluation of safety and cost of an open-design oxygen mask in a large community hospital. Respir Care 2018;63(4):412-416.
13. Yanez ND, Fu AY, Treggiari MM, Kirsch JR. Oropharyngeal oxygen concentration is dependent on the oxygen mask system and sampling location. Respir Care 2020;65(1):29-35.
14. Arnal JM, Garnero A, Saoli M, Chatburn RL. Parameters for simulation of adult subjects during mechanical ventilation. Respir Care 2018;63(2):158-168.
15. Wilson AM, Gray DM, Thomas JG. Increases in endotracheal tube resistance are unpredictable relative to duration of intubation. Chest 2009;136(4):1006-1013.
16. Gallagher CG, Sanii R, Younes M. Response of normal subjects to inspiratory resistive unloading. J Appl Physiol (1985) 1989;66(3):1113-1119.
17. Chatburn RL, Mireles-Cabodevil E. Handbook of respiratory care, 3rd ed. Sudbury, MA: Jones & Bartlett Learning; 2011.
18. Chen JZ, Katz IM, Pichelin M, Zhu K, Caillibotte G, Noga ML, et al. Comparison of pulsed versus continuous oxygen delivery using realistic adult nasal airway replicas. Int J Chron Obstruct Pulmon Dis 2017;12:2559-2571.
19. Zhou S, Chatburn R. Effect of the anatomic reservoir on low-flow oxygen delivery via nasal cannula: constant flow versus pulse flow with portable oxygen concentrator. Respir Care 2014;59(8):1199-1209.
20. Waldau T, Larsen VH, Bonde J. Evaluation of five oxygen delivery devices in spontaneously breathing subjects by oxygraphy. Anaesthesia 1998;53(3):256-263.