

Comparison of the OxyMask and Venturi mask in the delivery of supplemental oxygen: Pilot study in oxygen-dependent patients

Jaime M Beecroft BSc, Patrick J Hanly MD FRCPC ABSM

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BACKGROUND: The OxyMask (Southmedic Inc, Canada) is a new face mask for oxygen delivery that uses a small 'diffuser' to concentrate and direct oxygen toward the mouth and nose. The authors hypothesized that this unique design would enable the OxyMask to deliver oxygen more efficiently than a Venturi mask (Hudson RCI, USA) in patients with chronic hypoxemia.

METHODS: Oxygen-dependent patients with chronic, stable respiratory disease were recruited to compare the OxyMask and Venturi mask in a randomized, single-blind, cross-over design. Baseline blood oxygen saturation (SaO_2) was established breathing room air, followed in a random order by supplemental oxygen through the OxyMask or Venturi mask. Oxygen delivery was titrated to maintain SaO_2 4% to 5% and 8% to 9% above baseline for two separate 30 min periods of stable breathing. Oxygen flow rate, partial pressure of inspired and expired oxygen (PO_2) and carbon dioxide (PCO_2), minute ventilation, heart rate, nasal and oral breathing, SaO_2 and transcutaneous PCO_2 were collected continuously. The study was repeated following alterations to the OxyMask design, which improved clearance of carbon dioxide.

RESULTS: Thirteen patients, aged 28 to 79 years, were studied initially using the original OxyMask. Oxygen flow rate was lower, inspired PO_2 was higher and expired PO_2 was lower while using the OxyMask. Minute ventilation and inspired and expired PCO_2 were significantly higher while using the OxyMask, whereas transcutaneous PCO_2 , heart rate and the ratio of nasal to oral breathing did not change significantly throughout the study. Following modification of the OxyMask, 13 additional patients, aged 18 to 79 years, were studied using the same protocol. The modified OxyMask provided a higher inspired PO_2 at a lower flow rate, without evidence of carbon dioxide retention.

CONCLUSIONS: Oxygen is delivered safely and more efficiently by the OxyMask than by the Venturi mask in stable oxygen-dependent patients.

Key Words: Chronic obstructive pulmonary disease; Hypoxemia; Oxygen masks; Oxygen therapy; Respiratory failure

Patients with severe lung disease often require supplemental oxygen to maintain an adequate level of oxygen in the blood and adequate delivery of oxygen to vital organs (1). In patients with chronic hypoxemia, oxygen therapy is usually provided through nasal cannulae and can improve sleep and mood, increase mental alertness and stamina, enable an

Comparaison des masques OxyMask et Venturi pour l'administration de suppléments d'oxygène : Étude pilote chez des patients dépendants de l'oxygénothérapie

HISTORIQUE : L'OxyMask (Southmedic Inc., Canada) est un nouveau masque facial pour l'administration d'oxygène qui utilise un petit « diffuseur » pour concentrer et diriger l'oxygène vers la bouche et le nez. Selon l'hypothèse des auteurs, cette conception originale permettrait à l'OxyMask d'administrer l'oxygène plus efficacement que le masque Venturi (Hudson RCI, É. U.) chez les patients souffrant d'hypoxémie chronique.

MÉTHODES : Des patients atteints de maladie respiratoire chronique stable et dépendants de l'oxygénothérapie ont été recrutés afin de comparer l'OxyMask et le masque Venturi dans le cadre d'un protocole randomisé à simple insu avec permutation des groupes. La saturation du sang en oxygène (SaO_2) a été établie au départ à l'air ambiant, ensuite de manière aléatoire avec des suppléments d'oxygène administrés au moyen de l'OxyMask ou du masque Venturi. L'administration d'oxygène a été ajustée de manière à maintenir la SaO_2 entre 4 et 5 % et 8 et 9 % au-dessus des données de départ pendant deux périodes distinctes de 30 minutes de respiration stable. Le débit d'oxygène, la pression partielle de l'oxygène inspiré et expiré (PO_2) et du gaz carbonique (PCO_2), la ventilation par minute, la fréquence cardiaque, la respiration nasale et buccale, la SaO_2 et la PCO_2 transcutané ont été recueillis de manière continue. L'étude a été répétée après des modifications apportées au modèle de l'OxyMask qui ont amélioré l'élimination du CO_2 .

RÉSULTATS : Treize patients, âgés de 28 à 79 ans, ont été examinés au départ avec l'OxyMask original. Le débit d'oxygène était plus faible, la PO_2 inspirée était plus élevée et la PO_2 expirée était plus faible avec l'OxyMask. La ventilation par minute et la PCO_2 inspiré et expiré ont été significativement plus élevés avec l'OxyMask, tandis que la PCO_2 transcutane, la fréquence cardiaque et le ratio de respiration nasale vs orale n'ont pas changé significativement au cours de l'étude. Après la modification de l'OxyMask, treize autres patients âgés de 18 à 79 ans ont été étudiés au moyen du même protocole. L'OxyMask modifié a donné lieu à une PO_2 inspirée plus élevée avec un débit moindre, sans signe de rétention du CO_2 .

CONCLUSION : L'oxygène est administré sans danger et plus efficacement avec l'OxyMask qu'avec le masque Venturi chez les patients dépendants de l'oxygénothérapie dont l'état est stable.

oxygen-dependent patient to carry out activities of daily living, and prevent pulmonary hypertension and cor pulmonale (2). In patients with acute or acute-on-chronic hypoxemia, supplemental oxygen is usually administered through a face mask. One of the commonly used, conventional face masks for oxygen delivery is the 'Venturi' or air-entrainment system (1).

St Michael's Hospital, University of Toronto, Toronto, Ontario; Health Sciences Centre, University of Calgary, Calgary, Alberta
Correspondence: Dr Patrick J Hanly, 1421 Health Sciences Centre, 3330 Hospital Drive Northwest, Calgary, Alberta T2N 4N1.
Telephone 403-210-8694, fax 403-283-6151, e-mail phanly@ucalgary.ca

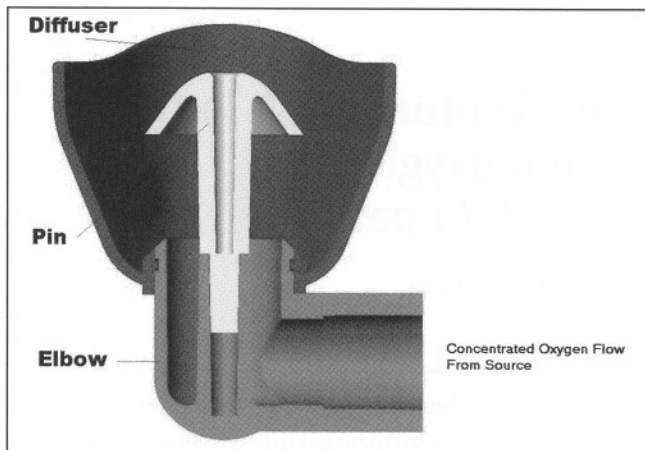


Figure 1 Cross-sectional drawing illustrating the shape of the cup that houses the pin diffuser of the OxyMask (Southmed Inc, Canada) system. Courtesy of Southmed Inc

While the Venturi mask is effective at delivering accurate oxygen concentrations (FiO_2), it requires relatively high oxygen flow rates to achieve this. The OxyMask (Southmed Inc, Canada) is a new face mask for oxygen delivery that uses a small 'diffuser' to concentrate and direct oxygen toward the nose and mouth, thereby delivering high concentrations of oxygen at a relatively low flow. We hypothesized that this system delivers oxygen more efficiently and more comfortably than the conventional Venturi mask. We studied this hypothesis by titrating supplemental oxygen in oxygen-dependent patients through an OxyMask and Venturi mask (Hudson RCI, USA) in a randomized, single-blind, cross-over design. Although the diffuser technology has been evaluated previously, this has predominantly been in healthy volunteers (3-5), in which the diffuser was placed in a plastic boom connected to a headset (OxyArm, Southmed Inc). Only one previous investigation has used the OxyArm in oxygen-dependent patients (6). However, the authors did not provide information about disease severity, including pulmonary function measurements and arterial blood gases. Consequently, it is unknown how disease severity, including the presence of chronic carbon dioxide retention, impacts the effectiveness of the diffuser technology. Moreover, the diffuser has not been evaluated while placed in a face mask. These differences in patient population and mask design may limit the application of this new technology in patients with severe lung disease. Consequently, we performed a pilot study on a group of stable oxygen-dependent patients to determine if the OxyMask can deliver oxygen safely and more efficiently than the Venturi system in this patient population.

METHODS

Patient recruitment

Patients aged 18 to 80 years with chronic pulmonary disease who were using supplemental oxygen, and whose oxygen requirement was stable (ie, did not change over a 3 h period at rest) were invited to participate in the study. Patients whose oxygen requirement was unstable (ie, changed hourly) and those who could not tolerate being off supplemental oxygen for 10 min were excluded. A detailed medical history and the most recent pulmonary function test and arterial blood gas measurements were obtained for each patient enrolled in the study. The study protocol was approved by the research ethics board at St Michael's Hospital (Toronto,

Ontario), and all patients gave written informed consent to participate.

OxyMask

The OxyMask uses a small diffuser, comprised of a cup and pin, to concentrate and direct oxygen toward the nose and mouth (Figure 1). Oxygen diffuses out from the inlet and pin in the shape of a mushroom. During inspiration, the shape of the diffuser causes complex velocity vortices to form, which forces oxygen into a flame-like shape toward the face. This dynamic property of the diffuser is unique to this oxygen delivery system and results in concentrated oxygen delivery during inspiration (3). The mask itself is comprised of a plastic mold, which covers the nose and mouth, and an elastic band to hold the mask in place (Figure 2A). The diffuser cup is positioned approximately 2 cm away from the nose and mouth. Two modified versions of the mask, which also employ the diffuser, combine the stability of a mask with an open oxygen delivery system, thereby reducing the likelihood for carbon dioxide retention to occur. In one modified version of the mask, the plastic mold is resected to create an open system while continuing to stabilize the diffuser cup and hold it in front of the face (Figure 2B). Another version is comprised of a rigid plastic brace in which the diffuser cup sits. An elastic band crosses the front of the brace, which allows it to rest comfortably on the chin and hold the cup in front of the face. The side arms of the brace sit below the ears and are secured by an adjustable elastic band that stretches behind the neck (Figure 2C).

Protocol

The study used a single-blind, randomized, cross-over design (Figure 3). All study measurements were performed during wakefulness in the seated, upright position. In each patient, baseline oxygen saturation (SaO_2) was established after breathing room air for 10 min (washout period). Following the washout period, 5 min of baseline measurements (outlined below) were obtained breathing room air. Stable SaO_2 during this 5 min period was required before proceeding. Patients then received supplemental oxygen for 60 min through either the OxyMask or Venturi mask, which were used in a random order. Oxygen delivery was titrated to maintain blood SaO_2 4% to 5% (low saturation) and 8% to 9% (high saturation) above baseline, each for 30 min of stable breathing. The order of targeting 'low saturation' and 'high saturation' was also randomized. Oxygen therapy was then discontinued and another set of baseline measurements was obtained breathing room air for 5 min after a second washout period. Patients then received supplemental oxygen therapy through the remaining mask (OxyMask or Venturi) for another 60 min following the same protocol described above.

During all phases of the study, recordings were obtained by continuous monitoring of abdominal and chest movement (Respirace, Ambulatory Monitoring Inc, USA); partial pressure of oxygen (PO_2) (Oxigraf, USA) and partial pressure of carbon dioxide (PCO_2) (Capnograph, BCI/Smiths Medical PM Inc, USA) at the lower lip; heart rate and oximetry (Mallinckrodt/Nellcor Puritan Bennett, USA); transcutaneous PCO_2 on the chest below the clavicle (Microgas, Kontron Instruments, United Kingdom); nasal and oral flow through a sensor placed on the upper lip (Ultima Dual Airflow Pressure Sensor, Braebon Medical Corporation, Canada); and oxygen flow rate (4100 Series, TCI Inc, USA) using a custom-made program (LabView 6.1, National Instruments, USA). Respirace was calibrated to reflect tidal volume using a custom-made program (LabView 6.1) according to specified criteria (7). SaO_2 was recorded from two oximeters with the probes placed on

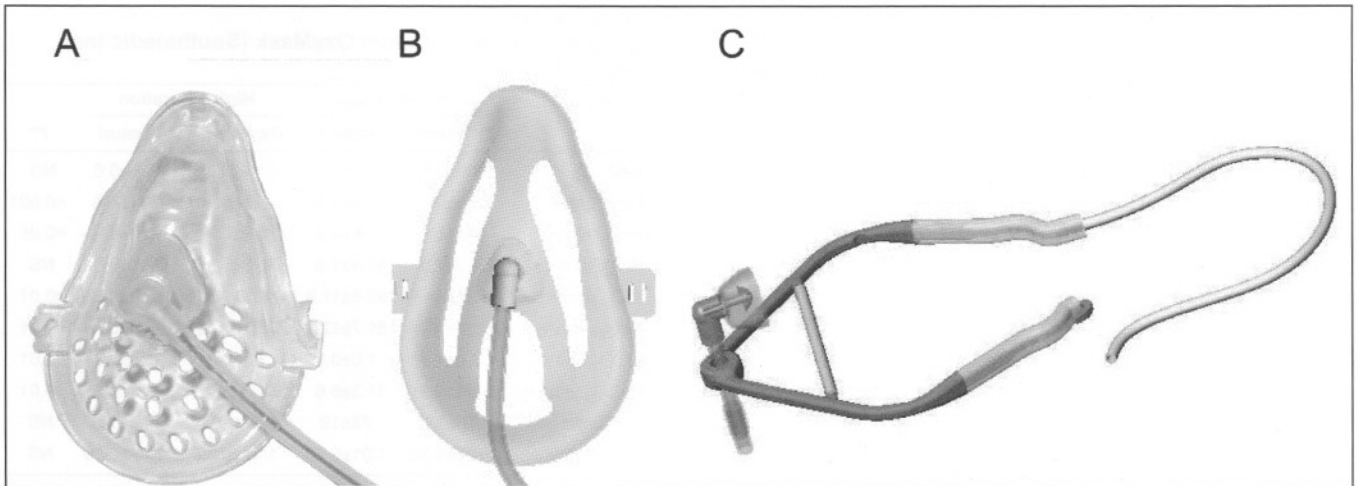


Figure 2) The OxyMask (Southmed Inc, Canada) oxygen delivery system. **A** Original OxyMask; **B** Modified OxyMask with plastic mold resected; **C** Modified OxyMask comprised of brace and elastic bands. Courtesy of Southmed Inc

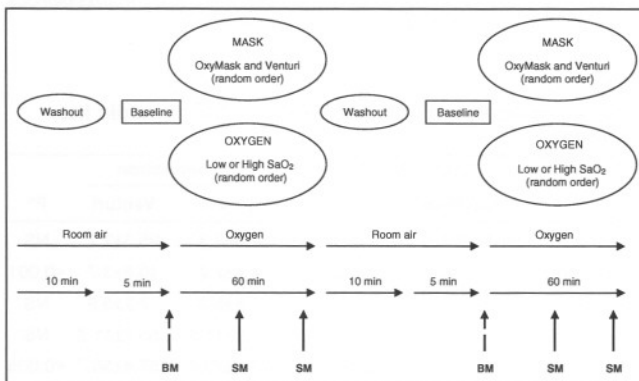


Figure 3) Study protocol comparing the OxyMask (Southmed Inc, Canada) with the Venturi mask (Hudson RCI, USA). BM Baseline measurements; SaO₂ Blood oxygen saturation; SM Study measurements

the patients' fingers (one on each hand) to overcome any potential technical issues with the measurement, such as poor peripheral circulation. Data were collected on a breath-to-breath basis and continuous measurements of tidal volume, respiratory rate, maximum and minimum PCO₂ and PO₂, maximum nasal and oral flow, and mean SaO₂, heart rate, transcutaneous PCO₂ and oxygen flow rate were obtained. The data for each respiratory measurement during 5 min of breathing room air (baseline measurements) (Figure 3) and during the last 15 min of each experimental condition (study measurements) (Figure 3) are reported as means $\pm$ SD.

Patients were instructed to comment on what they liked and disliked about each mask and to rate the comfort of each mask on a linear scale from zero to 10. Within this scale, a rating of zero indicated the mask was 'very uncomfortable', five indicated it was 'reasonably comfortable', and a rating of 10 indicated the mask was 'very comfortable'.

Once the first 13 patients were studied, a tendency for modest carbon dioxide retention associated with the OxyMask was noted. Consequently, the manufacturers modified the mask design (described above) to limit this tendency and the study was repeated in an additional 13 patients. Eight patients were studied using one modification (Figure 2B) and five patients were studied using the alternate modification (Figure 2C). Because both modifications were performed to address the same issue and the results with both

TABLE 1
Patient demographics

	Original OxyMask	Modified OxyMask
Patients, n	13	13
Male:female	4:9	5:8
Age, years	56 $\pm$ 16	60 $\pm$ 16
Body mass index, kg/m ²	35.0 $\pm$ 12.3	32.7 $\pm$ 9.2
O ₂ requirement (rest), L/min	2.3 $\pm$ 1.3	2.5 $\pm$ 1.2
O ₂ requirement (exercise), L/min	3.4 $\pm$ 1.6	3.4 $\pm$ 1.4

Data are presented as means $\pm$ SD unless otherwise indicated. There were no significant differences in patient demographics between those who used the original and those who used the modified OxyMask (Southmed Inc, Canada)

modified masks were almost identical, the data from this second set of patients were combined. The study protocol was the same as that used for the first set of patients. Humidification was not used throughout the study.

Analysis

Mean values of tidal volume, respiratory rate and minute ventilation, minimum and maximum PCO₂ and PO₂, maximum nasal and oral flow, heart rate, oxyhemoglobin saturation, oxygen flow rate and transcutaneous PCO₂ were calculated for each patient in each phase of the study. Mean SaO₂ for each phase was determined by averaging data from both oximeters. The ratio of maximum nasal to oral breathing was calculated during baseline measurements and, in each titration phase, it was expressed as a proportion of baseline measurements. Group mean data and standard deviations were analyzed using repeated measures ANOVA and the unpaired Student's *t* test (SPSS version 12.0, SPSS Inc, USA). *P* < 0.05 was considered statistically significant.

RESULTS

Patient demographics

Thirteen patients, aged 28 to 79 years, were studied using the original OxyMask. Thirteen additional patients, aged 18 to 79 years, were studied using the modified versions of the OxyMask. Table 1 shows the patient demographic data. All patients required supplemental oxygen at rest and during exercise. Patients studied using the original and modified versions

TABLE 2
Respiratory diagnosis

	Original OxyMask	Modified OxyMask
COPD	5	5
Hypoventilation syndrome		
Obesity	1	1
Obesity, COPD	1	1
Post-polio syndrome	1	0
Chest wall disease		
Kyphoscoliosis	1	1
Postesophageal surgery	1	0
Cystic fibrosis	2	1
Idiopathic pulmonary fibrosis	1	2
Bronchiectasis	0	1
Pulmonary hypertension	0	1

There were no significant differences in respiratory diagnoses between those who used the original and those who used the modified OxyMask (Southmedic Inc, Canada). COPD Chronic obstructive pulmonary disease

TABLE 3
Pulmonary function tests

	Original OxyMask		Modified OxyMask	
	Measured	Predicted (%)	Measured	Predicted (%)
Spirometry				
FVC, L	1.87±0.66	57.38±13.20	1.63±0.53	52.33±14.06
FEV ₁ , L	1.22±0.56	51.54±21.50	0.99±0.54	44.75±23.56
FEV ₁ /FVC, %	65.06±19.29	—	59.7±22.5	—
FEF50%, L/s	1.38±1.23	42.15±34.71	1.40±1.82	46.92±64.92
FEF75%, L/s	0.40±0.32	25.23±18.66	0.35±0.34	23.33±21.63
Vital capacity, L	2.00±0.80	60.20±15.05	1.66±0.58	53.89±13.33
ABG (room air)				
pH	7.40±0.05		7.40±0.04	
PCO ₂ , mmHg	47.58±6.07		51.08±14.46	
PO ₂ , mmHg	52.75±7.56		51.83±8.44	
SaO ₂ , %	87±6		86±7	
HCO ₃ ⁻ , mmol/L	30.00±4.07		31.83±7.49	

Data are presented as means ± SD. There were no significant differences in spirometry or arterial blood gases (ABG) between patients who used the original and those who used the modified OxyMask (Southmedic Inc, Canada). FEF50% Forced expiratory flow at 50% of vital capacity; FEF75% Forced expiratory flow at 75% of vital capacity; FEV₁ Forced expiratory volume in 1 s; FVC Forced vital capacity; HCO₃⁻ Bicarbonate concentration; PCO₂ Partial pressure of carbon dioxide; PO₂ Partial pressure of oxygen; SaO₂ Blood oxygen saturation

of the OxyMask had a variety of respiratory disorders, as outlined in Table 2. Table 3 shows the spirometry and arterial blood gas results. Sixteen patients (62%) had chronic hypercapnia, defined as PCO₂ greater than 45 mmHg from arterial blood gas measurements on room air. There were no significant differences in patient demographics, respiratory diagnoses or pulmonary function between patients who were studied using the original OxyMask and patients who were studied using the modified masks.

Mask efficiency

By study design, blood SaO₂ did not differ significantly between oxygen titrations using the original OxyMask or Venturi mask (Table 4). Oxygen flow rate was significantly lower while using the OxyMask during both low and high SaO₂ titrations. Oxygen flow was significantly higher for both

TABLE 4
Oxygen titration – original OxyMask (Southmedic Inc, Canada)

	Low saturation		High saturation		P*
	OxyMask	Venturi	OxyMask	Venturi	
SaO ₂ , %	92.0±3.6	91.7±3.4	94.8±3.2	94.9±3.6	NS
Flow, L/min	0.9±0.3	4.8±1.5	2.1±0.9	12.2±3.9	<0.001
Ve, L/min	9.1±5.0	7.4±4.2	10.6±5.9	8.0±4.4	<0.05
tCO ₂ , mmHg	51.9±8.9	51.4±7.6	51.3±9.1	52.4±8.0	NS
PiO ₂ , mmHg	229.7±44.5	192.6±11.9	459.5±167.5	330.0±126.6	<0.01
PeO ₂ , mmHg	164.4±16.9	181.7±12.2	209.2±39.2	266.9±52.4	<0.01
PiCO ₂ , mmHg	3.9±1.5	1.6±0.9	3.2±0.6	1.4±0.8	<0.01
PeCO ₂ , mmHg	33.5±8.9	11.3±5.6	27.2±8.9	11.6±8.0	<0.01
HR, beats/min	78±18	78±18	79±19	77±18	NS
Nasal:oral	1.20±0.32	1.01±0.26	1.11±0.22	1.07±0.26	NS

Data are presented as means ± SD. *OxyMask versus the Venturi mask (Hudson RCI, USA). HR Heart rate; Nasal:oral Ratio of nasal to oral breathing expressed as a proportion of the ratio at baseline; NS Not significant; PeCO₂ Expired partial pressure of carbon dioxide; PeO₂ Expired partial pressure of oxygen; PiCO₂ Inspired partial pressure of carbon dioxide; PiO₂ Inspired partial pressure of oxygen; SaO₂ Blood oxygen saturation; tCO₂ Transcutaneous partial pressure of carbon dioxide; Ve Minute ventilation

TABLE 5
Oxygen titration – modified OxyMask (Southmedic Inc, Canada)

	Low saturation		High saturation		P*
	OxyMask	Venturi	OxyMask	Venturi	
SaO ₂ , %	90.6±3.3	90.8±3.2	94.8±2.3	95.3±2.7	NS
Flow, L/min	1.8±0.6	5.2±2.7	4.4±2.2	10.8±3.7	<0.001
Ve, L/min	8.1±6.7	6.4±3.9	7.6±5.3	7.2±5.9	NS
tCO ₂ , mmHg	54.5±11.0	54.4±11.4	56.0±11.6	55.7±11.7	NS
PiO ₂ , mmHg	217.3±50.5	189.4±25.8	323.5±73.1	257.4±56.7	<0.005
PeO ₂ , mmHg	162.6±19.0	182.1±26.5	216.7±56.4	245.5±55.3	<0.01
PiCO ₂ , mmHg	2.4±1.6	1.2±0.9	2.4±1.8	1.4±0.8	<0.05
PeCO ₂ , mmHg	14.9±9.5	9.7±3.8	13.0±8.3	11.9±5.4	NS
HR, beats/min	86±16	85±17	85±16	83±15	NS
Nasal:Oral	1.04±0.54	1.10±0.69	0.97±0.55	1.01±0.58	NS

Data are presented as means ± SD. *OxyMask versus the Venturi mask (Hudson RCI, USA). HR Heart rate; Nasal:oral Ratio of nasal to oral breathing expressed as a proportion of the ratio at baseline; NS Not significant; PeCO₂ Expired partial pressure of carbon dioxide; PeO₂ Expired partial pressure of oxygen; PiCO₂ Inspired partial pressure of carbon dioxide; PiO₂ Inspired partial pressure of oxygen; SaO₂ Blood oxygen saturation; tCO₂ Transcutaneous partial pressure of carbon dioxide; Ve Minute ventilation

masks during high SaO₂ (P<0.001), and the difference in flow rate while using the OxyMask compared with the Venturi mask was greater during high SaO₂ (P<0.001). Inspired PO₂ was significantly higher and expired PO₂ significantly lower while using the OxyMask compared with the Venturi mask. Inspired and expired PO₂ were significantly higher during high SaO₂ (P<0.001), and the difference in PO₂ while using the OxyMask compared with the Venturi mask was greater during high SaO₂ (P<0.05). Minute ventilation and inspired and expired PCO₂ were significantly higher while using the original OxyMask than the Venturi mask. Transcutaneous PCO₂, heart rate and the ratio of nasal to oral breathing did not change significantly throughout the study.

Similarly, the study design required that there was no difference in blood SaO₂ during comparison of the modified OxyMask and the Venturi mask (Table 5). Oxygen flow rate

was significantly lower while using the modified OxyMask compared with the Venturi mask. Oxygen flow was significantly higher during high SaO_2 ($P<0.001$) and the difference in flow rate while using the modified OxyMask compared with the Venturi mask was greater during high SaO_2 ($P<0.001$). Inspired PO_2 was significantly higher and expired PO_2 significantly lower while using the modified OxyMask than the Venturi mask. Inspired and expired PO_2 were significantly higher during high SaO_2 ($P<0.001$) and the difference in inspired PO_2 while using the modified OxyMask compared with the Venturi mask was greater during high SaO_2 ($P<0.05$). Although inspired PCO_2 was significantly higher while using the modified OxyMask compared with the Venturi mask, the magnitude of the increase was approximately one-half that seen with the original OxyMask (Table 4). Furthermore, in contrast to what was found with the original OxyMask, minute ventilation and expired PCO_2 , in addition to transcutaneous PCO_2 , were not significantly different while using the modified OxyMask compared with the Venturi mask. Heart rate and the ratio of nasal to oral breathing did not change significantly throughout the study. Analysis of chronic hypercapnic patients alone showed similar results.

Mask satisfaction

There was a trend for a higher rating of mask comfort for the original OxyMask than for the Venturi mask, but this difference did not reach statistical significance (7.3 ± 2.4 versus 5.1 ± 2.5 [$P=0.07$] on the comfort scale, respectively). Similarly, ratings of mask comfort tended to be higher for the modified OxyMask than the Venturi mask, but this difference did not reach statistical significance (6.7 ± 1.9 versus 4.9 ± 2.4 , $P=0.09$). Favourable comments regarding the original and modified OxyMask were that it was quiet, light, and that it fit better, was less humid and less intrusive than the Venturi mask.

DISCUSSION

Previous work has suggested that the diffuser used in the OxyMask delivers oxygen more efficiently than conventional interfaces (3). However, this study was performed using the OxyArm, in which the diffuser was placed in a plastic boom connected to a headset, and measurements were obtained in healthy volunteers (3). Subsequent work evaluating the diffuser technology used either healthy volunteers, nonoxygen-dependent patients, or patients with chronic obstructive pulmonary disease of unknown severity, and did not evaluate the diffuser while placed in a face mask (4-6,8,9). These differences in patient population and interface design may limit the application of earlier findings to patients with chronic, severe respiratory disease. We thought it was important to evaluate this before studying the usefulness of the OxyMask in a large group of patients with hypoxemic respiratory failure. Consequently, we performed a pilot study to determine whether oxygen can be delivered safely and more efficiently through the OxyMask compared with the Venturi mask in oxygen-dependent patients. To control for the effect of short-term changes in underlying respiratory disease, we chose patients who were clinically stable and made detailed measurements over a relatively short period of time. We recruited a heterogeneous group of patients to determine whether our findings were consistent over a broad range of causes of oxygen dependency. Our study is the first to compare the efficiency of

the OxyMask with the Venturi mask in oxygen-dependent patients.

The study demonstrated a number of interesting findings. Both the original and modified OxyMask delivered oxygen effectively to oxygen-dependent patients with severe lung disease. Target oxyhemoglobin saturation was obtained using a lower oxygen flow rate than with the conventional Venturi mask, demonstrating that it is a more efficient oxygen delivery system. Peak inspiratory PO_2 was significantly higher while peak expiratory PO_2 was significantly lower using the OxyMask than while using the Venturi mask. These findings demonstrate the unique functionality of the OxyMask. During inspiration, complex vortices form as oxygen is released through the diffuser, and the concentration of oxygen is very high as it is drawn toward the nose and mouth. During expiration, oxygen diffuses away. Because of this unique function, the OxyMask does not require a reservoir to trap oxygen during expiration, nor does it require high oxygen flow rates to achieve a high FiO_2 . The original OxyMask did not allow adequate clearance of carbon dioxide away from the mask, as demonstrated by the rise in minute ventilation and higher PCO_2 . We attribute this to the fact that low oxygen flow rates and insufficient mask ventilation caused rebreathing to occur. This issue was corrected by the modifications to the OxyMask design, which employed a more open concept. Using the modified OxyMask, oxygen was delivered more efficiently, and although inspired PCO_2 remained elevated, the difference to the Venturi mask was modest and it was not associated with a rise in minute ventilation or transcutaneous PCO_2 . Consequently, clinically significant carbon dioxide retention does not occur with the modified OxyMask, even in patients with chronic hypercapnic respiratory failure (Table 3).

The Venturi mask is commonly used for oxygen delivery, particularly in patients in whom inappropriately high FiO_2 needs to be avoided (1). Oxygen is delivered at high velocity through a small orifice, and shear forces cause mixing of room air and oxygen (10). FiO_2 can be adjusted using mask adaptors of different orifice sizes. The flow of gas delivered to the patient always exceeds minute ventilation, which prevents entrainment of room air around the mask and dilution of oxygen, but the oxygen flow rate requires adjustment for each orifice size (1). Delivering oxygen at flow rates exceeding minute ventilation provides a target FiO_2 and also ensures adequate clearance of carbon dioxide (11). While accurate FiO_2 can be obtained and varied according to patient demand using the Venturi mask, the options are limited to a specific size and number of adaptors, and increasingly high oxygen flow rates are required to deliver higher FiO_2 .

The physical design of the OxyMask may provide additional benefits. The size and configuration of current face masks limit their suitability for prolonged use in acute hypoxemic respiratory failure (1). Although ratings of mask comfort were similar between the OxyMask and the Venturi mask on the comfort scale, patients also reported that the OxyMask was quiet, light and relatively nonintrusive, in contrast to the Venturi mask, which patients found to be noisy, bulky and intrusive. Further innovative modifications in how the OxyMask diffuser is presented and stabilized may make it acceptable for prolonged use in hospital. The OxyMask is also simpler to use than the Venturi mask because it does not require multiple adaptors. This provides a more flexible setup, which may appeal to care givers and also reduce costs.

CONCLUSIONS

The OxyMask delivers oxygen safely and more efficiently than the Venturi mask. The tendency for carbon dioxide retention that was evident in the prototype model has been corrected by modifications to the mask design. The OxyMask provides a low-flow, open oxygen delivery system, which can deliver a broad range of FiO_2 in a single setup. Further studies are required to define the clinical applications of this new technology in oxygen-dependent patients with acute and chronic respiratory failure.

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