# **EFFECT OF VARYING OXYGEN FLOW RATES ON THE DEVICE OUTPUT AND EFFECTIVE FiO2 OBTAINED AT DIFFERENT SETTINGS OF AIR ENTRAINMENT PORT OF SINGLE-UNIT VENTURI VALVE WITH MASK FOR OXYGEN THERAPY: A DESCRIPTIVE PILOT STUDY**

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#### **Abstract**

**Background:** The OxyMask 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 in patients with chronic hypoxemia. **Aim and objective: T**o determine if the OxyMask can deliver oxygen safely and more efficiently than the Venturi system in this patient population. **Method:** Oxygendependent 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 (SaO2) was established by breathing room air, followed in a random order by supplemental oxygen through the OxyMask or Venturi mask. Oxygen delivery was titrated to maintain SaO2 4% to 5% and 8% to 9% above baseline for two separate 30-minute periods of stable breathing. Oxygen flow rate, partial pressure of inspired and expired oxygen (PO2) and carbon dioxide (PCO2), minute ventilation, heart rate, nasal and oral breathing, SaO2, and transcutaneous PCO2 were collected continuously. The study was repeated following alterations to the OxyMask design, which improved clearance of carbon dioxide. **Result:** Using the original OxyMask, 16 patients between the ages of 30 and 70 were initially investigated. When utilizing the OxyMask, there was a decrease in oxygen flow rate, an increase in inspired PO2, and a decrease in expired PO2. While utilizing the OxyMask, minute ventilation as well as inspired and expired PCO2 were significantly greater. However, transcutaneous PCO2, heart rate, and the ratio of nasal to oral breathing did not alter significantly during the course of the trial. 16 additional patients, ranging in age from 30 to 70, were investigated utilizing the same technique after the OxyMask was modified. Without exhibiting any signs of carbon dioxide retention, the improved OxyMask produced a greater amount of inspired PO2 at a

lower flow rate. **Conclusion:** 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

### **Introduction**

Modern management of the sick patient involves the administration of oxygen in supposedly known concentrations. There are many delivery systems commercially available whose performances are documented in the literature [1–2]. This is usually reported as the actual delivery from the system [3], the resultant inspired concentration of oxygen [4–5], or the arterial oxygenation achieved. From a physics perspective, the actual concentration of oxygen delivered is determined by the interaction between the delivery system and the patient's breathing pattern [4]. In contrast, most of the in vivo measurements that have been reported were carried out in normal subjects breathing at rest or trained to vary their tidal volumes [6–7]. Several of these studies do point out that there are multiple factors that may compromise the performance of these devices and result in an effective FiO2 that is less, or occasionally more, than expected [4, 6].

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 [8]. 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 oxygen-dependent patient to carry out activities of daily living, and prevent pulmonary hypertension and cor pulmonale [9]. 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 [8]. While the Venturi mask is effective at delivering accurate oxygen concentrations (FiO2), it requires relatively high oxygen flow rates to achieve this. 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 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, crossover design. Although the diffuser technology has been evaluated previously, this has predominantly been in healthy volunteers [10–12], in which the diffuser was placed in a plastic boom connected to a headset (OxyArm, Southmedic Inc.). Only one previous investigation has used the OxyArm on oxygen-dependent patients [13]. 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 to patients with severe lung disease. We studied 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.

### **Method and Material**

Participants in the research included patients with chronic pulmonary illness, aged 30 to 70, who were receiving supplemental oxygen and whose oxygen need was stable, that is, did not fluctuate over the course of three hours at rest. Patients who were unable to tolerate not receiving supplemental oxygen for ten minutes or whose oxygen needs fluctuated hourly were omitted. Every patient who was enrolled in the study had a thorough medical history, the results of their most recent pulmonary function test, and measures of their arterial blood gas.The study protocol was approved by the research ethics board at Saifee Hospital, Mumbai, and all patients gave written informed consent to participate.

# **Oxy Mask**

The OxyMask concentrates and directs oxygen into the mouth and nose using a tiny diffuser made of a cup and a pin. From the intake and pin, oxygen diffuses outward in the form of a mushroom. The diffuser's design creates intricate velocity vortexes during inspiration, which push oxygen toward the face in the form of a flame. Concentrated oxygen delivery occurs during inspiration due to the diffuser's dynamic feature, which is exclusive to this oxygen delivery system (3). The mask itself is made out of an elastic band to keep the mask in place and a plastic mold that covers the mouth and nose. The diffuser cup is placed about two centimeters from the mouth and nose. 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 resectioned to create an open system while continuing to stabilize the diffuser cup and hold it in front of the face. 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 no. 1: Study protocol comparing the OxyMask with the Venturi Mask BM Baseline measurements; SaO2; blood oxygen saturation; SM Study measurements

### **Protocol**

A randomized, cross-over, single-blind design was employed in the study (Figure 1). All study measurements were taken when the subjects were awake and in an upright, seated position. Following ten minutes of inhaling room air (the washout phase), the baseline oxygen saturation (SaO2) for each subject was determined. After the washout time, room air was breathed for five minutes to acquire baseline readings (see below). Before continuing, stable SaO2 was needed for the full five minutes. The OxyMask or Venturi mask, which were employed in random sequence, was then utilized to give the patients extra oxygen for 60 minutes. The amount of oxygen delivered was adjusted to keep blood SaO2 levels between 4% and 5% (low saturation) and 8% and 9% (high saturation) above baseline during 30 minutes of steady breathing. Prioritizing "low saturation" and "high saturation"

Oxygen therapy was then discontinued, and another set of baseline measurements was obtained after breathing room air for 5 minutes after a second washout period. Patients then received supplemental oxygen therapy through the remaining mask (OxyMask or Venturi) for another 60 minutes, following the same protocol described above. During all phases of the study, recordings were obtained by continuous monitoring of abdominal and chest movement (Respitrace, Ambulatory Monitoring Inc., USA); partial pressure of oxygen (PO2) and partial pressure of carbon dioxide (PCO2) at the lower lip; heart rate and oximetry; transcutaneous PCO2 on the chest below the clavicle; nasal and oral flow through a sensor placed on the upper lip; and oxygen flow rate using a custom-made program. Respitrace was calibrated to reflect tidal volume using a custom-made program according to specified criteria (7). SaO2 was recorded from two oximeters with the probes placed on 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 minutes of breathing room air (baseline measurements) (Figure 3) and during the last 15 minutes 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'.

Following the examination of the first 16 patients, an OxyMask-related tendency for mild carbon dioxide retention was identified. As a result, the producers changed the mask's design (as previously mentioned) to lessen this propensity, and 16 more patients participated in the trial. One alteration was used to study eight patients, whereas the other modification was used to study five individuals. The data from this second set of patients was pooled because both modifications were made to address the same problem, and the outcomes with both changed masks were nearly equal. The study followed the same protocol as it did with the initial group of patients. The study was conducted without the use of humidification.

### **Statistics**

Mean values of tidal volume, respiratory rate, 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. The 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 23.0, SPSS Inc., USA). P<0.05 was considered statistically significant.

# **RESULTS**

# **Patient demographics**

16 patients, aged 30 to 70 years, were studied using the original OxyMask. 16 additional patients, aged 20 to 70 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 of the OxyMask had a variety of respiratory disorders, as highlighted 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.

# **Table No. 1: Patient Demographics**



Data show 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.

### **Table No. 2: Respiratory Diagnosis**



There were no significant differences in respiratory diagnoses between those who used the original and those who used the modified OxyMask. COPD: chronic obstructive pulmonary disease

### **Table No. 3: Pulmonary Function Tests**





Data are presented as means  $\pm$  SD. There were no significant differences in spirometry or arterial blood gases (ABG) between patients who used the original OxyMask and those who used the modified OxyMask. FEF50% Forced expiratory flow at 50% of vital capacity; FEF75% Forced expiratory flow at 75% of vital capacity; FEV1 Forced expiratory volume in 1s; FVC Forced vital capacity; HCO3: bicarbonate concentration; PCO2: partial pressure of carbon dioxide; PO2: partial pressure of oxygen; SaO2 blood oxygen saturation

### **Table no. 4: Oxygen titration—original OxyMask**



Data are presented as means  $\pm$  SD. \*OxyMask versus the Venturi mask. HR Heart rate; Nasal:oral The ratio of nasal to oral breathing expressed as a proportion of the ratio at baseline NS Not significant; PeCO2 experienced partial pressure of carbon dioxide; PeO2 experienced 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 no. 5: Oxygen titration—modified OxyMask**



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Data are presented as means  $\pm$  SD. \* OxyMask versus the Venturi Mask HR Heart rate; Nasal:oral The ratio of nasal to oral breathing expressed as a proportion of the ratio at baseline NS Not significant; PeCO2 experienced partial pressure of carbon dioxide; PeO2 experienced 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

### **Mask efficiency**

According to the study design, there was no discernible difference in blood SaO2 between oxygen titrations using the Venturi mask and the original OxyMask (Table 4). The OxyMask dramatically reduced the oxygen flow rate during both low and high SaO2 titrations. During high SaO2, oxygen flow was significantly higher for both masks (P<0.001), and there was a bigger difference in flow rate while using the OxyMask compared to the Venturi mask (P<0.001). When utilizing the OxyMask instead of the Venturi mask, inspired PO2 was much greater and expired PO2 was significantly lower. High SaO2 resulted in considerably higher inspired and expired PO2 (P<0.001) and a larger differential in PO2 while using the OxyMask compared to the Venturi mask (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, when comparing the modified OxyMask and the Venturi mask, the study design stipulated that there could not be a change in blood SaO2 (Table 5). When utilizing the modified OxyMask instead of the Venturi mask, the oxygen flow rate was noticeably reduced. High SaO2 resulted in significantly higher oxygen flow (P<0.001) and a larger flow rate difference while using the modified OxyMask compared to the Venturi mask (P<0.001). Compared to the Venturi mask, the improved OxyMask produced considerably higher inspired and expired PO2 values. During high SaO2, inspired and expired PO2 were considerably higher  $(P<0.001)$ , and there was a bigger difference in inspired PO2 while wearing the modified OxyMask compared to the Venturi mask  $(P<0.05)$ .

Although inspired PCO2 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). Moreover, utilizing the

modified OxyMask in comparison to the Venturi mask did not significantly alter minute ventilation, expired PCO2, or transcutaneous PCO2, which is in contrast to the findings with the original OxyMask. During the research, there was no significant change in heart rate or the ratio of nasal to oral breathing. Analyses conducted on chronic hypercapnic individuals by themselves produced comparable findings.

### **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  $(7.6\pm1.4)$ versus 5.58±0.85 [P=0.00008] 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  $(7.1 \pm 1.52 \text{ versus } 5.2 \pm 0.95, P =$ 0.00019). Favorable comments regarding the original and modified OxyMask were that it was quiet, light, and fit better; it was less humid and less intrusive than the Venturi mask.

# **DISCUSSION**

According to earlier research, the OxyMask's diffuser distributes oxygen more effectively than traditional interfaces [13]. However, the OxyArm was used in this study, and measurements were taken on healthy participants with the diffuser inside a plastic boom that was attached to a headset [13]. Either healthy volunteers, nonoxygen-dependent patients, or patients with chronic obstructive pulmonary disease of unclear severity were utilized in later studies testing the diffuser technology; the diffuser was not evaluated while wearing a face mask [11–15]. The applicability of prior findings to patients with chronic, severe respiratory diseases may be limited by these variations in patient population and interface design. We believed it was critical to assess this prior to researching the OxyMask's utility in a large group setting. 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 heterogenous 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 oxygendependent patients. A similar study by Beecroft and Hanly et al. found that oxygen is delivered safely and more efficiently by the OxyMask than by the Venturi mask in stable oxygen-dependent patients. [16]. T. A. J. Wagstaff et al. It was found that the respiratory rate was increased, and its effect on the oxygen concentration was assessed. Variable performance systems such as the Hudson mask deliver a significantly reduced oxygen concentration at high respiratory rates. Fixedperformance systems delivering 24–40% oxygen deliver appropriate oxygen concentrations across the range of respiratory rates, whereas those delivering 60% show a reduction in performance. High-flow systems show no failure of performance at increased respiratory rates. [17]

Several intriguing findings were presented by the study. Patients with serious lung diseases who were oxygen-dependent were successfully given oxygen using both the

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original and improved OxyMasks. It is a more effective oxygen delivery device, as evidenced by the fact that target oxyhemoglobin saturation was reached at a lower oxygen flow rate than with the traditional Venturi mask. When utilizing the OxyMask instead of the Venturi mask, peak inspiratory PO2 was substantially higher and peak expiratory PO2 was significantly lower. These results highlight OxyMask's distinct capabilities. As the diffuser releases oxygen during inspiration, intricate vortexes emerge, and the oxygen concentration rises as it is dragged toward the mouth and nose. 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 FiO2. 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 PCO2. We attribute this to the fact that low oxygen flow rates and insufficient mask ventilation caused rebreathing to occur. The OxyMask design was modified to use a more open idea, which resolved this problem. The OxyMask was changed to provide oxygen more efficiently. Although inspired PCO2 remained raised, the difference from the Venturi mask was not as great, and neither was it linked to an increase in transcutaneous PCO2 or minute ventilation. Thus, even in individuals with persistent hypercapnic respiratory failure, the modified OxyMask does not result in clinically significant carbon dioxide retention (Table 3).

The Venturi mask is frequently used to supply oxygen, especially to patients where it is necessary to prevent unnecessarily high FiO2 [8]. A tiny opening allows oxygen to be delivered quickly, and shear forces mix oxygen with ambient air [18]. By employing mask adaptors with varying orifice sizes, FiO2 can be changed. In order to avoid room air entrainment around the mask and oxygen dilution, the gas flow rate given to the patient is always greater than minute ventilation [8]. However, the oxygen flow rate needs to be adjusted for every size orifice.In addition to providing a goal of FiO2, delivering oxygen at flow rates higher than minute ventilation guarantees sufficient carbon dioxide clearance [19]. With the Venturi mask, precise FiO2 may be measured and adjusted based on patient demand; however, the number and size of adaptors that can be used restrict the alternatives, and higher FiO2 requires higher oxygen flow rates.

The physical design of the OxyMask may provide additional benefits. The suitability of face masks for extended usage in acute hypoxemic respiratory failure is limited by their size and shape [8]. While patients found the Venturi mask to be bulky, noisy, and invasive, they also indicated that the OxyMask was silent, light, and generally nonintrusive. These rates of mask comfort were similar between the OxyMask and the Venturi mask. The OxyMask diffuser might be suitable for long-term usage in hospitals with some creative adjustments to how it is positioned and stabilized. Because it just needs one adapter instead of several, the OxyMask is also easier to use than the Venturi mask. This lowers costs and offers a more flexible configuration that can be appealing to caregivers.

### **Conclusion**

The OxyMask is a safer and more effective oxygen delivery system than a Venturi mask. Changes made to the mask design have eliminated the prototype model's apparent predisposition for carbon dioxide retention. A low-flow, open oxygen delivery device called OxyMask may supply a variety of FiO2 in a single setup. To

determine the practical uses of this novel technology in oxygen-dependent patients with both acute and chronic respiratory failure, more research is necessary.

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