



Fluidic Mustache Oxymizer® by CHAD® Therapeutics

Model F-224



Drive Medical Design & Manufacturing · 99 Seaview Blvd · Port Washington, NY · 11050
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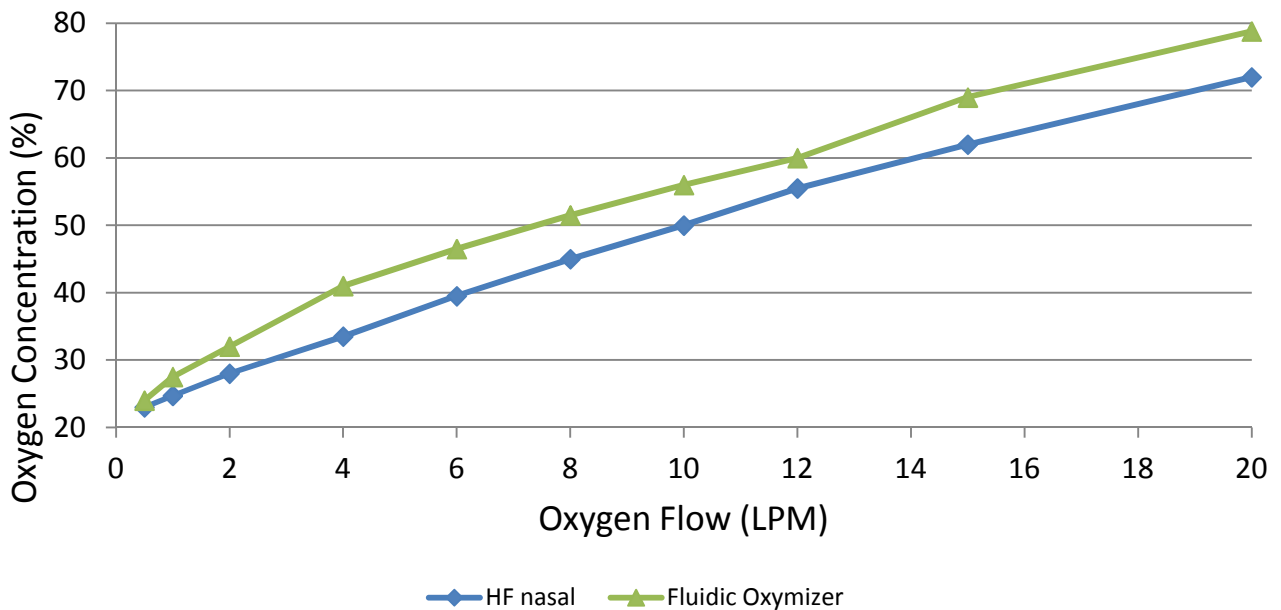
Fluidic Oxymizer® Overview

The Oxymizer® is the simplest conserving device available today, operating without electronics, batteries or flow controls. Development of this model of the Oxymizer® draws on over 30 years of research, development, and industry experience. The design of the Oxymizer® provides a more comfortable alternative to high LPM cannulas or non-rebreather masks. Further, it facilitates continued oxygen therapy while patients eat, drink and speak in an unobstructed manner, thereby reducing patient anxiety and the risk of desaturation. The Oxymizer® has been historically effective at oxygenating hard-to-saturate patients, including some with refractory hypoxemia.

Oxygen Delivery Efficacy

As illustrated below, the oxygen concentration of the bolus delivered from the Fluidic Oxymizer® is higher at every liter per minute setting, as compared to a high flow nasal cannula. During testing, FiO_2 was measured at the trachea of a head extension model of a mechanical lung with an I:E ratio of 1:1, 16.5 BPM, and tidal volume of 500 ml. Please note actual FiO_2 will vary with rate and depth of breath.

Oxygen Concentration at the Trachea via Fluidic Oxymizer and Hi-Flo Nasal



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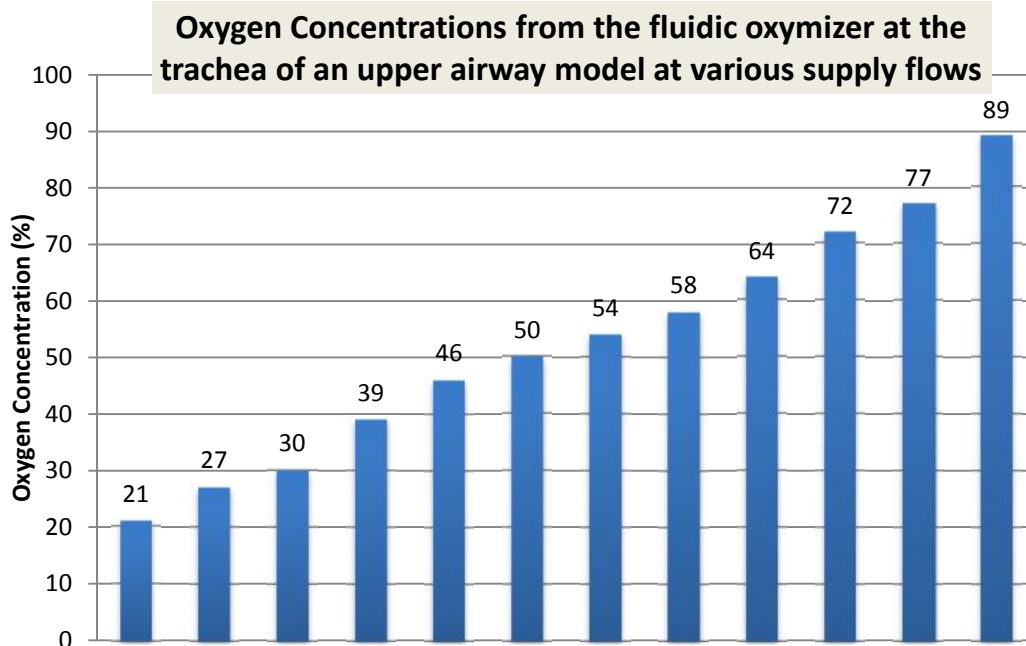
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The tracheal oxygen concentration study was performed with a face and nose model, calibrated oxygen analyzer with probe, calibrated mechanical syringe, oxygen cylinder with regulator calibrated to 15 LPM, PowerLab and LabChart electronic physiological recorder, and Excel and PowerPoint software.

The oxygen analyzer probe was inserted into a port in the trachea of the anatomically proportioned model (Figure 1). Oxygen was delivered at flows ranging from 1-15 LPM with the lung simulator cycling at 16.5 breaths per minute. The output of the oxygen analyzer was connected with the input of the ADInstruments PowerLab running LabChart software. The entire measurement was taken twice. The expectation is that the oxygen concentrations in the trachea would increase both during low flow (<8 LPM) as well as high flow (>8 LPM). Additionally, transitions from low flow to high flow were expected to be seamless. It was further anticipated that the high flow setting could deliver oxygen concentrations similar to those expected from a non-rebreather mask.



The Fluidic Oxymizer cycles well up to 12 LPM as measured by the oxygen analyzer probe situated in the reservoir housing near the exhaust ports. At 15 LPM the supply oxygen overwhelms the exhaust port region rendering cycling difficult to measure at that location since it is sensing high oxygen concentrations. However, when placed in the naris, cycling can be detected. The tracheal concentrations rise steadily with increasing oxygen supply flows. At 15 LPM the tracheal concentration is in the range of those measured with the non-rebreather mask. This is a similar finding observed when



working with patients who have a very high flow requirement. With a flow rate of 15 LPM combined with the fluidic reservoir, patients are able to receive equivalent oxygen therapy up to 20 LPM.

When testing the cycling of the Oxymizer®, the oxygen analyzer probe was inserted into a hole poked through the reservoir housing near the exhaust ports. (Figure 2). Oxygen was delivered at flows ranging from 0.5-15 LPM with the lung simulator cycling at 16.5 breaths per minute. The output of the oxygen analyzer was connected with the input of the ADInstruments PowerLab running LabCharts software. The entire measurement was taken twice. The expectation is that inhalation brings room air to the oxygen analyzer probe while exhalation brings pure oxygen to the probe. Cycling is expected to produce large variations of oxygen concentration from room air to nearly 100%. It is realized that there will be some mixing with ambient air.

Figure 1

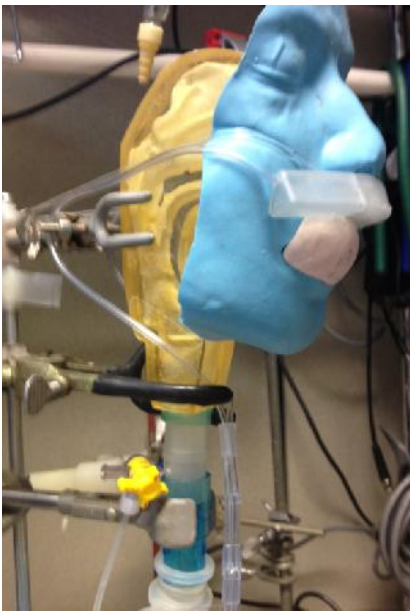


Figure 2



A NEW OXYGEN-CONSERVING DELIVERY DEVICE

B.L. TIEP, MD, M.J. BELMAN, MD, C. MITTMAN, MD, R.E. PHILLIPS AND B. OTSAP

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Recent multi-centered studies have demonstrated the value of low-flow oxygen therapy in hypoxemic patients with chronic obstructive pulmonary disease (COPD). Adequate correction of hypoxemia can improve the length and quality of life.

We most often prescribe oxygen through a nasal cannula. The oxygen flows continuously throughout the respiratory cycle. It is generally agreed that the greatest benefit of oxygen delivery occurs early in the inspiratory phase of respiration, with most of the remaining oxygen being lost to the atmosphere. It would be reasonable to postulate that if we could concentrate all delivery into the first one-third to one-half of inspiration, we might be able to reduce the oxygen flow requirement of the patient to around a quarter of the original requirement. This sort of reduction in oxygen requirement might be especially useful to patients who are taking portable oxygen; in such patients the weight, bulk, and especially the financial cost of the oxygen source becomes of critical importance.

In an attempt to concentrate oxygen delivery to the initial portion of inspiration, we designed a device which has a close-coupled reservoir, which stores 20 ml of oxygen during expiration and delivers that stored quantity during early inspiration. It was designed to be lightweight, low-cost and disposable. The system is operated by the patient, using the respiratory pressure changes at the nose.

DESCRIPTION OF DEVICE

The oxygen-conserving delivery device* consists of nasal prongs, a close-coupled reservoir and a lariat oxygen conduit (Figure 1). The reservoir portion of the device covers the face in a mustache distribution. During exhalation, the initial dead space air fills the chamber. Because



Figure 1. The Oxymizer™ oxygen-conserving device.

*Oxymizer™ oxygen-conserving device, Chad Therapeutics, Inc., Woodland Hills, CA

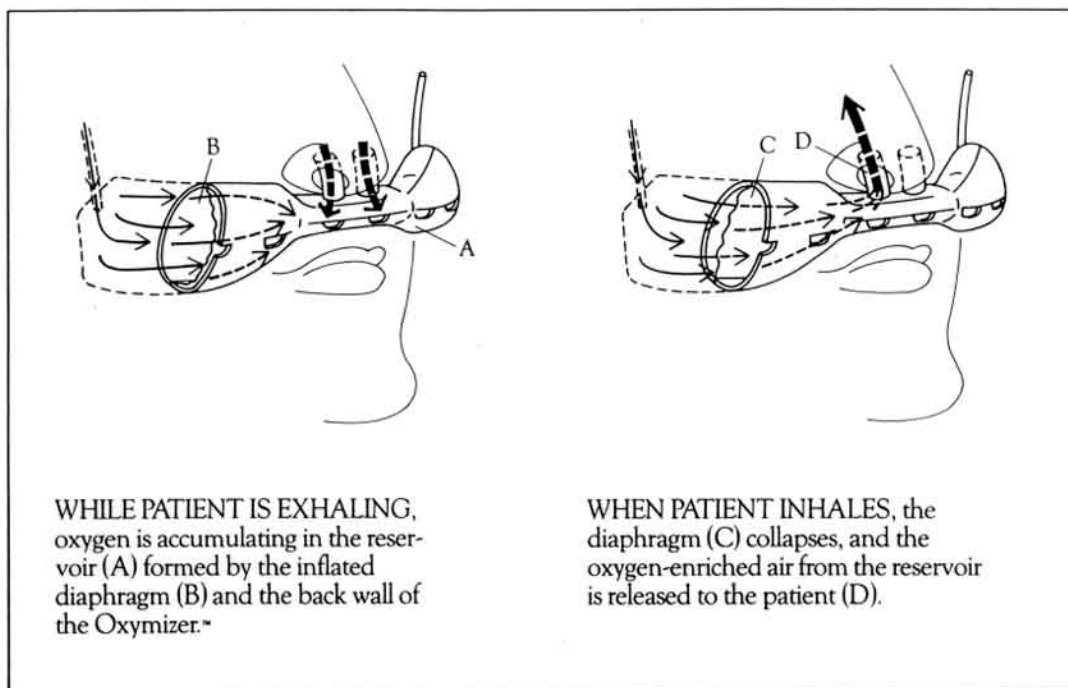


Figure 2.

there is no further room for exhaled air, the rest of exhalation overboards co-lateral to the nasal prongs. Meanwhile, during that ensuing portion of exhalation, oxygen which enters laterally displaces the original exhaled (dead space) gas

medially and passes out through the nasal prongs. (See Figure 2). The effect of the foregoing is that when the patient is ready to inhale, 20 ml of oxygen-enriched gas may be easily displaced during the early portion of inhalation.

TABLE I
DEMOGRAPHIC DATA

Subject	Sex	Age	FVC ₁	FEV ₁	FEV/FVC(%)
W.B.	M	66	2.3	0.7	30
M.M.	M	64	3.6	1.0	29
C.C.	M	63	1.9	0.5	26
H.H.	F	69	1.7	0.4	24
D.T.	F	73	2.4	0.7	29
C.O.	M	57	2.3	0.6	26
C.H.	M	74	2.3	0.7	30
A.S.	M	71	3.4	0.9	26
V.W.	F	63	2.0	0.6	30
M.W.	F	67	1.6	0.5	31
mean		66.7±5.2	2.3±0.7	0.66±0.18	28.1±2.4

TABLE II
INDIVIDUAL OXYGEN SATURATION DATA

	M.W	V.W	A.S.	C.H.	C.O.	D.T.	H.H.	C.C.	M.M.	W.B.	\bar{x}	SD
Standard Cannula												
R/A	89.9	90.5	92.7	88.5	94.5	91	78	91	89.5	90.5	89.5	4.4
0.5	91.0	92.5	93.2	89.7	94.8	92	88	93	91	91.5	91.3	1.9
1.0	93.2	93.5	93.8	91.6	95.7	92.2	89.5	94	92	93.5	92.9	1.7
2.0	95	94.5	96.2	92.4	96.2	93.2	93	96	93.5	95.5	94.6	1.4
3.0	95.7	95.7	96.7	93.7	97.7	94.2	94	97.2	95	96	95.6	1.4
4.0	96	97.2	97.2	94.5	98.2	95	94.5	98	96	97	96.4	1.4
Conservor Device												
0.5	94	94.2	96.7	91.7	96.7	93.2	92.5	96.2	93	94.5	94.3	1.8
1.0	94.8	95.2	97.2	93.6	97.4	94	94	97	94	95	95.2	1.5
1.5	94.7	95.7	97	94.5	97.7	94.2	94.5	97.5	94.5	95.5	95.6	1.3
2.0	96	96.5	97.2	95	98.2	94.5	95	98	95	96.5	96.2	1.3

METHODS

Ten patients with stable chronic obstructive lung disease who are hypoxemic either at rest or exercise were asked to volunteer for the study. Their mean age was 66.7 years, ranging from 57 years to 74 years; their mean FEV₁ was .66±.18 L. On each of these subjects we measured oxygen saturation at room air, 0.5, 1, 2, 3 and 4 L/min through the standard nasal cannula and 0.5, 1, 1.5 and 2 L/min using the conservor device. We always went back to room air samples between device changes to reestablish our baseline. The order of choice as to the steady flow cannula or conservor was randomized. We always started with the lowest flow and increased incrementally. We determined the time required for equilibrations at each supply flow and added 2 minutes to insure equilibration. We used a spirometrically calibrated rotometer accurate to ±0.05 L/min to meter the supply oxygen flow. We used a Biox II A ear oximeter to measure oxygen saturation. We compared the conservor with the steady flow cannula via analysis of variance.

RESULTS

The mean room air saturation was 89.5±4.4%. The mean saturation at 0.5 L/min supply flow was 91.7±1.9% for the standard cannula and 94.3±1.8% for the conservor. At 1.0 L/min the mean saturation was 92.9±1.7% for the standard cannula and 95.2±1.5% for the conservor. At 2 L/min the saturation was 94.6±1.4% for the standard cannula and 96.2±1.3% for the conservor. At 3 L/min the mean saturation was 95.6±1.4%, and at 4 L/min it was 96.4±1.4%, both of these measurements via the standard cannula. The differences in oxygen saturation between the two were compared using an analysis of variance and found to be statistically significant (P<.0001).

In Figure 3 we have compared the oxygen saturations achieved by the conservor versus the saturations achieved by the standard cannula for supply flows of 0.5, 1.0, and 2.0 L/min. In each case oxygen saturation was improved using the conservor.

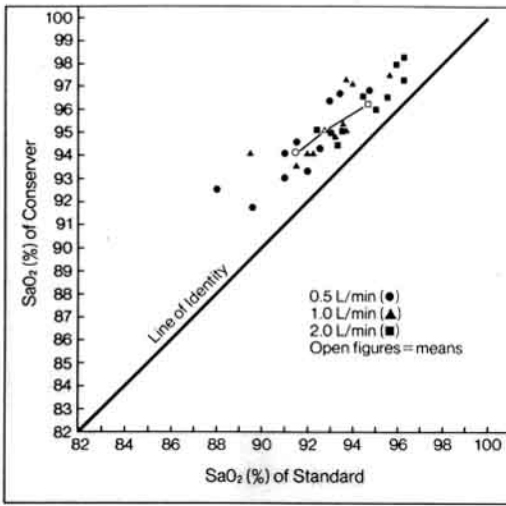


Figure 3. Oxygen saturations at various supply flows achieved by conserver and standard nasal cannula.

In Figure 4, one may again compare oxygen saturations for each subject at 0.5, 1.0 and 2.0 L/min, the first point in each panel representing the standard cannula and the second point representing the conserver at the same supply flow. The open figures represent the means. Again, oxygen saturation is improved by the conserver in each case. Figure 5 represents the

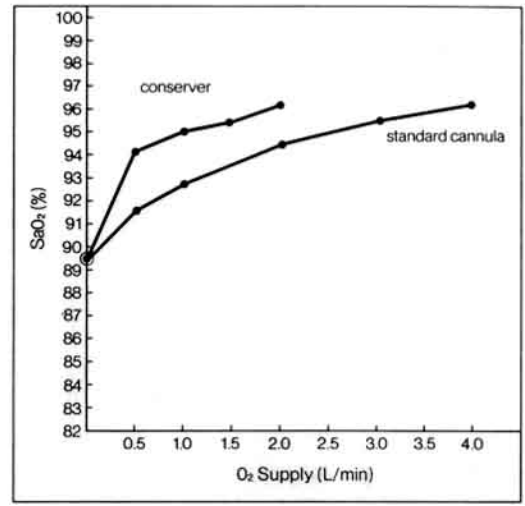


Figure 5. Comparison of oxygen saturation curves.

oxygen saturation curves for the standard cannula and the conserver. When the supply flow to the conserver is 0.5 L/min, the saturation is equivalent to the standard cannula at 1.8 L/min. However, when the supply flow to the conserver is increased to 1 L/min, the saturation is equivalent to the standard cannula at 2.5 L/min. Using the conserver at a supply flow of 2 L/min,

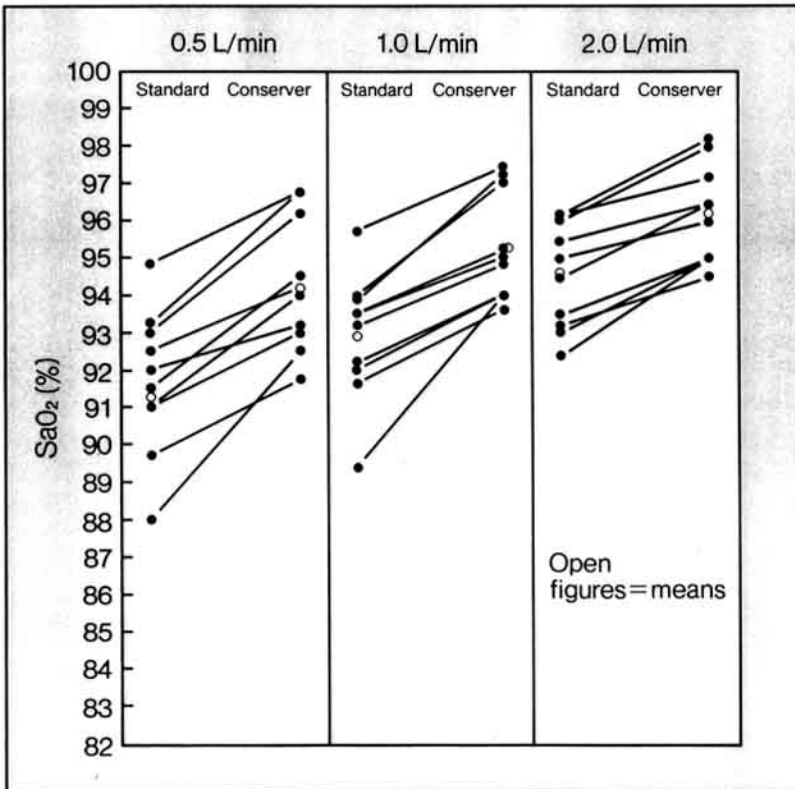


Figure 4. Comparison of oxygen saturations @ oxygen supply flows of 0.5, 1.0 and 2.0 L/min.

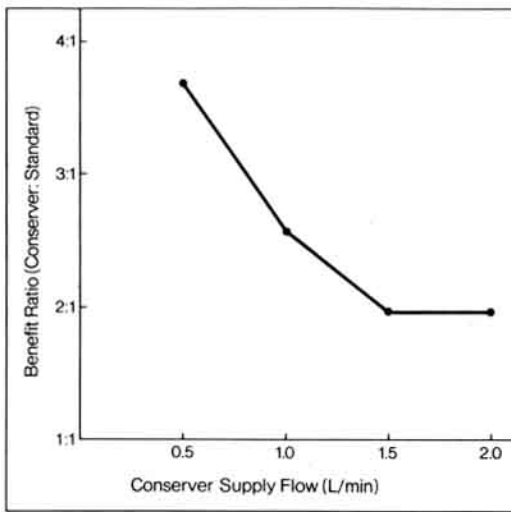


Figure 6. Mean benefit ratios (conserver: standard) at 0.5, 1.0, 1.5 and 2.0 L/min.

the saturation is equivalent to 4 L/min by the standard cannula. The benefits of using the conserver as compared to the standard cannula at different supply flows can be seen in Figure 6. At 0.5 L/min, the conserver provides a 3.7:1 benefit mean (range = 2.5:1 to 6:1) over the standard cannula; however, as the conserver supply flow is increased to 2 L/min, the conserver benefit reduces to 2:1 over the standard cannula.

DISCUSSION

The advantage of the conserver over conventional cannulas is that it saves oxygen and thus enables patients to sustain prescribed oxygen levels on substantially less oxygen. For portable oxygen therapy, patients will be able to use lighter, more portable oxygen sources and the transfill compressed systems become practical alternatives to the more expensive liquid systems. The goal of therapy is to achieve a PO_2 greater than 60mm or oxygen saturations of 90%. Complete correction of hypoxemia is never the goal of therapy, since oxygen content is not improved substantially beyond that point. The conserver required only 0.5 L/min to achieve adequate saturations. The disadvantages of the conserver lie in the fact that patients must breathe through their nose in order to drive the system and that this device is more obtrusive, covering the face in a mustache distribution. Patients, however, have been finding the conserver more comfortable than the

standard cannula because it is soft and the weight is distributed more evenly. For portable oxygen delivery, it becomes a trade-off between a smaller, less bulky and cheaper oxygen source and a large device covering the mustache area.

We recommend further studies to evaluate the ability of the conserver to humidify inspired gas. Longer-term patient acceptance studies and exercise studies are also recommended.

CONCLUSIONS

1. The oxygen-conserving delivery device can provide effective oxygen delivery at substantially reduced supply flows.
2. Greater benefit occurs at lower supply flows, with the benefit ratio for the saturation at .5 L/min being 3.7:1 and at 2 L/min it is reduced to 2:1.
3. The conserver is disposable, and it could significantly reduce the cost of oxygen therapy.

OXYMIZER and OXYMIZER Pendant
Disposable Oxygen Conserving Devices

DESCRIPTION AND RATIONALE

OXYMIZER and OXYMIZER Pendant devices are simple, disposable oxygen conservers. The use of these products allows healthcare professionals to maintain adequate oxygen saturations in hypoxic patients while using significantly lower oxygen flow rates than required by traditional means.

By reducing the oxygen flow rate necessary to achieve adequate oxygen saturations, these devices reduce by 50% to 75% the amount of oxygen required to treat a patient successfully. The benefits of this conservation include:

- Reduced oxygen costs
- Increased ambulation by making portable systems last significantly longer
- Reduced nasal irritation and dryness, eliminating the need for humidification in most patients
- Use of low flow oxygen concentrators on patients who require higher flow rates than their existing concentrators provide
- Ability to adequately saturate higher flow oxygen patients more comfortably, eliminating the need for an oxygen mask.

These conservers accumulate and store, in a 20ml reservoir, the oxygen that is usually wasted during exhalation. A highly responsive membrane within the reservoir acts as a reflux to force the accumulated oxygen, together with the reduced oxygen flow, into the lungs quickly. This occurs at the very beginning of inhalation – the optimal time to deliver supplemental oxygen.

The delivery of this 20ml bolus of oxygen at the very beginning of inhalation allows the healthcare professional to reduce the oxygen flow rates required to obtain target oxygen saturations. For example, in the first half second of inhalation (the time period during which all the oxygen that takes part in the gas exchange reaches the distal portion of the lungs), a patient who requires 2 l/m oxygen by traditional means receives the same amount of oxygen and achieves the same blood oxygen saturations when the oxygen is delivered at .5 l/m via the OXYMIZER devices. One l/m via OXYMIZER is equivalent to 3 l/m via standard cannula and 2 l/m is equivalent to 4 l/m via traditional means. These equivalencies have been confirmed in more than (30) worldwide clinical studies in a variety of circumstances and clinical conditions.

Two versions of the OXYMIZER device are available. Both work on the same reservoir principal and provide similar oxygen saturations and savings. The original OXYMIZER places the reservoir directly under the patient's nose. Although patients report that this is the more comfortable of the two styles, its configuration makes it too obtrusive for some patients. The OXYMIZER Pendant version incorporates the reservoir system in the cannula tubing and a circular chamber resembling a pendant that rests against the patient's chest. This chamber can be concealed easily under clothing, making it much less obtrusive than the original OXYMIZER device; however, it is not quite as comfortable. Many patients use both styles – they wear the original OXYMIZER when they are in the privacy of their homes and the OXYMIZER Pendant when they go out.

USE OF A RESERVOIR NASAL CANNULA IN HOSPITALIZED PATIENTS WITH REFRACTORY HYPOXEMIA

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Purpose: The purpose of this study was to determine if a reservoir nasal cannula could effectively replace an oxygen mask in hospitalized patients who require a high FiO_2 ($\geq .50$) and who do not require endotracheal intubation or mechanical ventilation. These patients are often alert and could eat, utilize incentive spirometry for deep breathing, experienced fewer episodes of transient hypoxemia, and be more comfortable if the oxygen mask could be replaced by a nasal cannula. However, conventional nasal cannulae usually deliver less than 50% oxygen and are not effective in correcting hypoxemia in these patients.

Methods: We studied ten consecutive patients who were clinically stable for at least 24 hours and who were receiving $\geq 50\%$ oxygen by mask using an oxygen blender and a flow of at least 80L/min (high-flow system) with SpO_2 of 91-92%. The patients were then switched to a reservoir nasal cannula (**Oxymizer**[®] by CHAD THERAPEUTICS, INC.) with flow adjusted from 6L to 8L/min to attempt to match the SpO_2 level being achieved by the oxygen mask. Twenty-four hours later the acceptability of the reservoir cannula was assessed by each patient.

Results: In nine of ten trials, the **Oxymizer**[®] provided equal SpO_2 levels, with FiO_2 ranging from .50 to .65 by mask. In one subject receiving 65% oxygen, the highest SpO_2 achieved with the **Oxymizer**[®] was 86%. Assessment of the patients after 24 hours indicated that in all subjects there was unequivocal preference for the **Oxymizer**[®] nasal cannula.

Conclusion: A reservoir nasal cannula can be used to correct hypoxemia in most patients requiring an FiO_2 of .50 or greater. The **Oxymizer**[®] was more comfortable and clinically preferable to an oxygen mask.

Clinical Implications: The use of a reservoir cannula should be considered as an alternative to a mask in hospitalized patients who have refractory hypoxemia and require 50% or more oxygen.

Evaluation of an Oxygen-Conserving Nasal Cannula

Brian L Tiep MD, Brooke Nicotra MD, Rick Carter PhD,
Robert Phillips, and Ben Otsap MS

Multicenter long-term oxygen therapy trials have established that low-flow oxygen is beneficial to hypoxemic patients with chronic obstructive pulmonary disease (COPD). A large percentage of these patients receive oxygen via steady-flow nasal cannula (SNC). Because of the rising cost of medical care and particularly the cost of oxygen therapy, we designed an oxygen-conserving nasal cannula (CNC). In a previous study, we demonstrated by ear oximetry that the CNC required substantially less oxygen to achieve adequate oxygen saturation than did the SNC. In this paper we describe the principles of operation of the CNC and present data comparing the CNC and SNC. Methods: We studied 4 subjects with COPD, simultaneously measuring SaO₂ by ear oximetry and SaO₂ and PaO₂ by standard blood analysis, with the subjects breathing first room air and then supplemental oxygen at 0.5, 1.0, and 2.0 L/min with both the SNC and CNC. Ten minutes was allowed between tests for equilibration. Results: The CNC achieved significantly higher ($P < 0.001$) saturations than did the SNC at equivalent oxygen supply flows. Absolute improvements in PaO₂ were 10.9 torr at 0.5 L/min, 18.2 torr at 1.0 L/min, and 27 torr at 2 L/min. There was a high correlation between ear oximetry and blood analysis readings. Conclusion: We conclude that the widespread use of the CNC could result in a significant financial savings while increasing the range and portability of oxygen therapy devices. (Respir Care 1985;30:19-25.)

Introduction

Deterioration of lung function due to chronic bronchitis, emphysema, and pulmonary fibrosis is a problem of growing magnitude. Often, deterioration leads to a patient's becoming hypoxemic, at which

time the clinician will consider prescribing supplemental oxygen, usually at low flowrates through a nasal cannula. There is usually considerable value in providing such a patient with supplemental oxygen. (It has been shown to be beneficial when hypoxemia is accompanied by an oxygen saturation of less than 90%).¹ The British² and NOTT³ studies showed that survival could be improved if oxygen was provided at night while the patient was sleeping and that survival could be prolonged even further by oxygen therapy approaching 24 hours per day. Other studies have demonstrated that low-flow oxygen therapy reduces pulmonary hypertension, polycythemia, and depression and improves cor pulmonale and psychomotor skills. Based on the results of the cited studies, 15 to 18 hours of oxygen may be as efficacious as 24 hours, provided the patient receives oxygen while asleep and during exercise.

Dr Tiep, Mr Phillips, and Mr Otsap are in the Department of Respiratory Disease, City of Hope National Medical Center, Duarte, California. Dr Nicotra and Dr Carter are at the University of Texas Health Science Center, Tyler, Texas. This work was made possible in part by support from the James J Roberts Research Fund and by Chad Therapeutics of Woodland Hills, California.

Reprints: Brian L Tiep MD, Department of Respiratory Disease, City of Hope National Medical Center, 1500 East Duarte Rd, Duarte CA 91010.

The actual required flow of nasal oxygen is usually quite small. For example, 2 L/min will increase the inspired oxygen percentage from 20.9% (atmospheric) to approximately 27%.^{7,8} A small increment of oxygen can make an enormous difference to the well-being of many hypoxemic patients because it raises arterial saturation to a physiologically acceptable level. Many of these patients then improve to the point at which a portable oxygen source becomes a consideration.

Providing supplemental oxygen to ambulatory patients presents unique problems. Portable oxygen is expensive. Its cost usually ranges from \$200 to \$1,000 per month, with the average around \$300.^{9,10} A portable oxygen source capable of providing 2 L/min is relatively heavy and bulky. The weight of a typical liquid-oxygen canister that lasts about 8 hours at 2 L/min ranges from 9 to 14 pounds, and cylinders of that weight will last less than 4 hours. Smaller and lighter gas cylinders are available, but they last only about 2 hours at 2 L/min. So unless a flow of 1 L/min or less is prescribed, most patients require the large cylinder or the liquid-oxygen canister, both of which must usually be transported on a cart rather than strapped over the shoulder of the often weak and debilitated user. In addition to the heavy, bulky canister that the patient must transport, the nasal cannula can be a source of discomfort to the patient. Pressure and rubbing often cause chronic inflammation and at times the breakdown of tissue at the nares, nasal bridge, and earloop-contact areas.

Conventional oxygen delivery via nasal prongs is inefficient and wasteful because oxygen flows continuously throughout the respiratory cycle even though exhalation constitutes 60 to 70% of the cycle. When one considers that the anatomical dead space at end expiration is filled with alveolar gas that constitutes the first one third of the volume of the next breath to reach the alveoli, and that the last one third of an inspired resting tidal volume serves to fill the anatomical dead space, one realizes that only 15 to 20% of the respiratory cycle brings fresh gas to the alveolar level where it can participate in gas exchange. As a result, most continuous-flow oxygen is lost to the atmosphere. If oxygen delivery could be confined to early inspiration, the oxygen requirement would be reduced considerably and that would translate to a reduction in the weight and bulk of equipment and the cost of oxygen.

Other investigators have examined methods of delivering oxygen during inhalation.¹¹⁻¹³ Altman and Block¹¹ and Flick et al,¹² using experimental devices with nasal-pressure sensing and solenoid valves to deliver oxygen during inspiration, were able to reduce oxygen consumption by 20 to 50%. Other similar devices, most of which sense the beginning of inhalation via pressure changes transmitted through the oxygen conduit, have come to our attention. However, the device used by Robert et al¹³ had a thermistor attached to a specialized cannula at the nasal prongs to sense the crossover between exhalation and inhalation, and by this technique these investigators were able to reduce the oxygen flowrate to half that required by the steady-flow cannula.

We have taken a different approach by designing a cannula that stores oxygen during exhalation and delivers it during inhalation.^{14,15} It is composed of a reservoir that is closely coupled to the nasal prongs and into which oxygen flows continuously at a low flowrate. During exhalation, oxygen builds up in the reservoir, and the next inspiration delivers a bolus of oxygen-enriched gas in addition to the continuous low-flow oxygen. A lower oxygen flow is required to achieve adequate saturation because of the addition of this bolus of oxygen during inspiration. We have previously used ear oximetry to establish the efficacy of the oxygen-conserving nasal cannula (CNC).^{14,15} In this paper we will describe the CNC and its principles of operation and then, using arterial blood gas analysis and CO-Oximetry data in addition to ear oximetry, compare the CNC and a standard steady-flow nasal cannula (SNC).

The Oxygen-Conserving Nasal Cannula (CNC)

Physical Description

The Oxymizer CNC,* shown in Figure 1, is composed of nasal prongs, a closely coupled 20-ml reservoir with a collapsible membrane, and an oxygen supply line at the distal end of the reservoir on each side.^{14,15} The conserver cannula with its reservoir is positioned under the nose and above the upper lip and extends laterally to the cheeks. The oxygen

*Suppliers are identified in the Product Sources section at the end of the text.

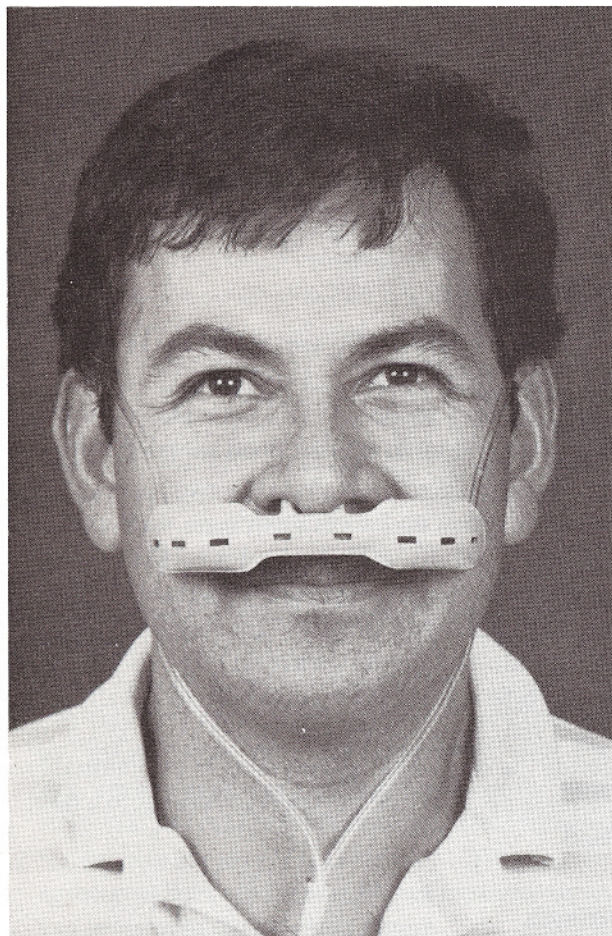


Fig. 1. The oxygen-conserving nasal cannula, consisting of nasal prongs, closely coupled reservoir with an internally collapsible membrane, and oxygen supply tubing. On exhalation, 20 ml of oxygen is stored in the reservoir. On inhalation, the stored oxygen is added to the steady flow already being supplied, thus increasing the FIO_2 .

supply lines attached to both ends of the reservoir extend laterally over the ears and merge into a single supply tube similar to that of most cannulas. The system requires at least minimal nasal breathing to trigger its operation.

Principles of Operation

The CNC (Fig. 1) stores oxygen in the following manner: During early exhalation, the dead space gas pushes the reservoir membrane out, allowing the reservoir to start filling with oxygen, which enters from the lateral ends and flows medially, toward the nasal prongs. During the remainder of exhalation,

oxygen displaces the original dead space gas, venting it through the nasal prongs. When the patient next inhales, he receives a 20-ml bolus of oxygen-enriched gas in addition to the steady-flow oxygen.

Oxygen-Delivery Model

Figures 2 & 3 present a model of oxygen delivery. For this presentation we assumed a respiratory rate of 20 breaths per minute and an I/E of 1:2. Both figures depict families of oxygen supply curves, with the base curve representing steady flow through an SNC. Figure 2 shows the calculated volume of oxygen (from all sources) in 200 ml of gas received at the threshold of the airway in 0.5 seconds with each of three different supply flows. Both room-air—and supplemental—oxygen contributions are included. Similarly, Figure 3 shows the calculated percentage of oxygen (from all sources) in 200 ml of gas received at the threshold of the airway in 0.5 second with the same three supply flows. It should be noted in Figure 3 that the percentages of inspired oxygen provided with the use of the steady-flow cannula are those one would expect with that device (eg, 1 L/min = 24% and 2 L/min = 27%). The curves that are labeled "SR" (storage reflux) in the figures were calculated at the additional volume (Fig. 2) and high-

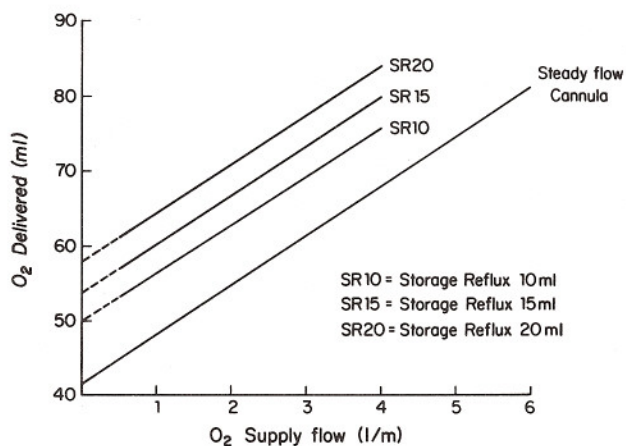


Fig. 2. Model of oxygen delivery, based on the assumptions that the patient is breathing 20 breaths per minute with the I/E being 1:2, that the first 200 ml of gas delivered to the threshold of the airway is important to alveolar ventilation, and that 0.5 second is required to inspire that volume. Shown are the effective oxygen volumes received by the patient via steady-flow cannula and via conserver cannula with additional 10, 15, and 20 ml oxygen boluses.

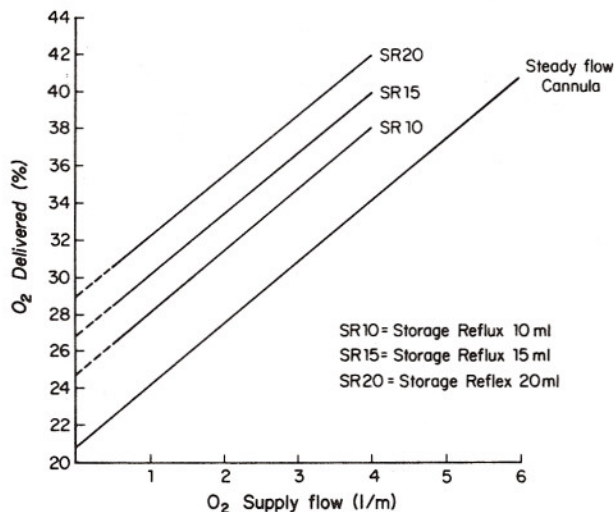


Fig. 3. Model of oxygen delivery, based on the assumptions that the patient is breathing 20 breaths per minute with an I/E of 1:2, that the first 200 ml of gas delivered to the threshold of the airway is important to alveolar ventilation, and that 0.5 second is required to inspire that volume. Shown are the effective oxygen concentrations received by the patient via steady-flow cannula and via conserver cannula with additional 10, 15, and 20 ml oxygen boluses.

er percentage (Fig. 3) of received oxygen resulting from the inclusion of 10, 15, and 20 ml of reservoir oxygen stored during 2 seconds of exhalation. The actual gain from the reservoir storage reflux via the CNC was less than calculated at the lower oxygen flowrates because of some mixing of 100% oxygen with dead space gas exhaled into the reservoir at the beginning of exhalation. However, at higher oxygen flows, such as 2 L/min, the actual gain was close to the calculated gain because the mixed gases were washed out by the supply oxygen. Also, at the higher flows there was some oxygen lost to the atmosphere through overboarding because the resulting volume of oxygen exceeded the limited storage volume of the reservoir; thus, the improvement ratio of the CNC to the SNC was smaller at the higher flows.

Clinical Study

Subjects

We recruited four subjects from the inpatient Chronic Respiratory Disease Service at the University of Texas Health Science Center at Tyler. Each subject had obstructive lung disease as determined

by spirometry ($FEV_1 < 0.9$ L and $FEV_1/FVC\% < 60$). The subjects gave their written informed consent consistent with the standards of the Center's Institutional Review Board. The only change in the clinical management of these patients was the withholding of inhaled bronchodilators for 1 hour prior to the study.

Materials

We used a Biox IIA ear oximeter to measure oxygen saturation noninvasively and an Instrumentation Laboratory Model 282 CO-Oximeter to measure oxygen saturation in arterial blood samples. Arterial PO_2 was measured in duplicate by two Instrumentation Laboratory blood gas analyzers, with each instrument carefully calibrated prior to the introduction of each sample. We used an indwelling radial artery cannula with a 3-way stopcock to withdraw arterial blood samples conveniently. The oxygen supply flow was metered with a spirometrically calibrated rotometer accurate to within ± 0.05 L/min. During the study, the subjects were in a comfortable, reclining position and movement was kept to a minimum.

Methods

Using ear oximetry readings and analyses of arterial blood samples taken simultaneously, we compared the CNC and SNC at room-air oxygen and 0.5, 1.0, and 2.0 L/min of supplemental oxygen. The order of use of the two cannulas was randomized, but flow settings started at the lowest level and were incrementally increased to the highest level. We allowed at least 10 minutes between cannulas for the return to baseline on room air. We determined the equilibration time at each flow level and then added 2 minutes as insurance. Statistical comparisons were made by analysis of variance, followed by the Duncan multiple-comparison technique.

Results

Saturation and PaO_2 can be seen in Table 1. Figure 4 compares mean PO_2 levels achieved by the two cannulas at 0.5, 1.0, and 2.0 L/min oxygen supply; absolute improvements were 10.9 torr at 0.5 L/min, 18.4 torr at 1 L/min, and 27 torr at 2 L/min. At each

EVALUATION OF OXYGEN-CONSERVING NASAL CANNULA

Table 1. Mean Oxygen Saturations and Arterial Oxygen Pressures (PaO₂) with Standard Nasal Cannula (SNC) and Conserver Nasal Cannula (CNC) at 0.5, 1.0, and 2.0 L/min Supplemental Oxygen

Supplemental O ₂ Flow	Ear Oximeter Saturation (%)	CO-Oximeter Saturation (%)	PaO ₂
None (room air)	89.0 ± 3.3	90.4 ± 2.9	53.5 ± 5.3
0.5 L/min			
SNC	91.8 ± 2.0	92.3 ± 1.4	58.6 ± 4.3
CNC	94.1 ± 1.4	94.6 ± 2.3	69.5 ± 8.2
1.0 L/min			
SNC	93.4 ± 2.3	94.2 ± 2.5	65.6 ± 9.6
CNC	95.9 ± 0.8	96.8 ± 1.5	84.0 ± 10.2
2.0 L/min			
SNC	95.2 ± 1.2	96.1 ± 1.9	75.4 ± 7.0
CNC	97.4 ± 0.8	98.0 ± 1.5	102.4 ± 19.6

flow, oxygenation was significantly better ($P < 0.001$) with the CNC than with the SNC. Likewise, as can be seen in Figures 5 and 6, which compare the two cannulas through ear oximetry and CO-Oximetry, respectively, saturation was better with CNC. The curves in Figures 5 and 6 look quite similar, suggesting a similarity between these two techniques for measuring oxygen saturation. The degree of agreement between the readings of the two oximeters can be seen in the graph in Figure 7, on which both sets of saturation measurements are plotted.

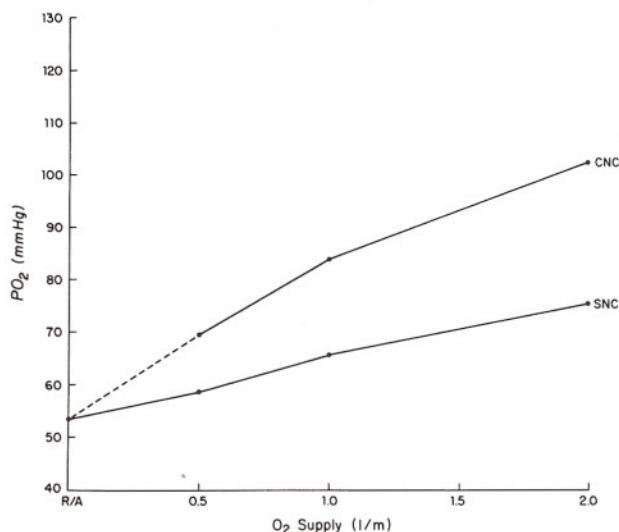


Fig. 4. Mean PO₂ values with the conserver nasal cannula (CNC) and the standard nasal cannula (SNC).

Discussion

In this study we used arterial PO₂ analyses, CO-Oximetry, and ear oximetry to compare the conserver cannula with the steady-flow cannula. Although better oxygenation resulted from supplemental oxygen administration through both types of cannulas, the CNC provided greater improvement as measured by all three techniques. We caution the reader to remember that the study was performed with only four subjects. However, these results confirmed our earlier findings, with ear oximetry alone,^{14,15} that the mean benefit ratio of the CNC to the SNC was greater than 3:1. As to the advisability of using an ear oximeter to compare the CNC with the SNC, a previous study¹⁶ has established a close relationship and a cross-predictive value between the oxygen saturation values obtained by arterial blood gas analysis and those obtained by ear oximetry. This study confirms this relationship. Additionally, the ear oximeter provides continuous measurement that makes trend analysis convenient. Our observation of patients in this and other studies revealed that patient body movement, coughing, and talking cause momentary peaks and troughs in saturation. A small percentage change in saturation, particularly below 90%, corresponds to a large change in PO₂. The small variability can be easily detected on a continuous ear oximeter printout, and a mean value can be determined by averaging peaks and troughs. Conversely, the PO₂ measured in a single blood sample might reflect the peak or trough extreme. Despite the fact

EVALUATION OF OXYGEN-CONSERVING NASAL CANNULA

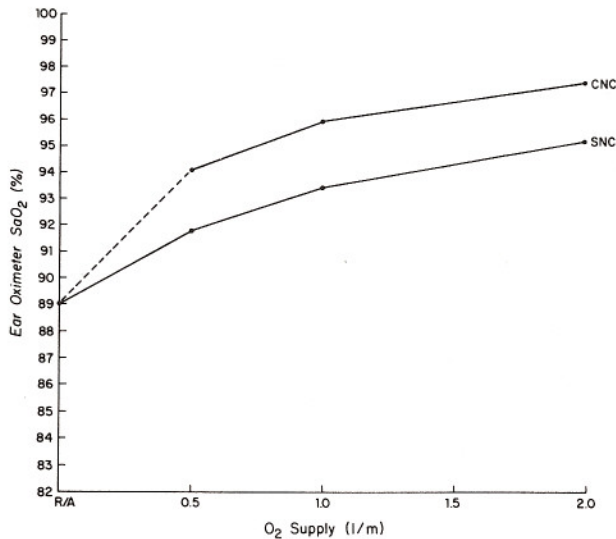


Fig. 5. Mean oxygen saturation values with the conserver cannula (CNC) and the standard nasal cannula (SNC), as measured by ear oximeter.

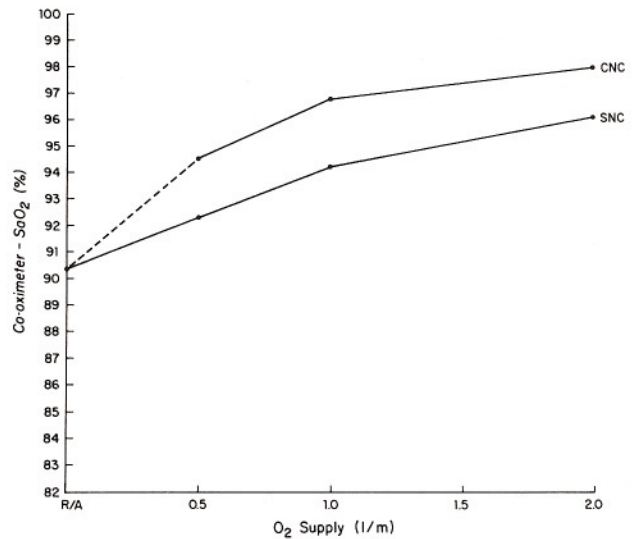


Fig. 6. Mean oxygen saturation values with the conserver nasal cannula (CNC) and the standard nasal cannula (SNC), as measured by CO-Oximeter.

that a small change in oxygen saturation can represent a large change in PaO₂, an argument can be made that ear oximetry readings represent the actual trend more accurately than do single blood gas measurements, particularly if a digital voltmeter is used, which increases the accuracy by a significant digit. These considerations, added to the ease of application of the oximeter probe and the fact that arterial cannulation is unnecessary, make ear oximetry an attractive method of comparing oxygen-delivery devices.

The most common oxygen prescription is 2 L/min, and the average patient breathes between 16 and 20 breaths per minute with a typical inspiration/expiration ratio of about 1:2. The CNC was designed to provide the same benefit at 0.5 to 1.0 L/min that the SNC provides at 2 L/min. By referring to Figure 2, one can see that to accomplish this goal, the CNC must store 16.6 ml of oxygen during exhalation and be able to deliver this bolus to the threshold of the airway in the first half second of inhalation. The reservoir's storage capacity is 20 ml; therefore the calculated benefit ratio of the CNC to the SNC is greatest at 0.5 L/min. Actually, there is some mixing of oxygen and dead space gas in the reservoir at 0.5 L/min (eg, at 0.5 L/min the oxygen concentration in the reservoir is approximately 85% and at 2 L/min it is about 97%), but this mixing decreases as the sup-

ply flow increases. Because the CNC and its reservoir are also supplied with steady-flow oxygen, the oxygen in the storage reservoir is an extra benefit. However, because the benefit is additive rather than proportional, and because there is reservoir over-

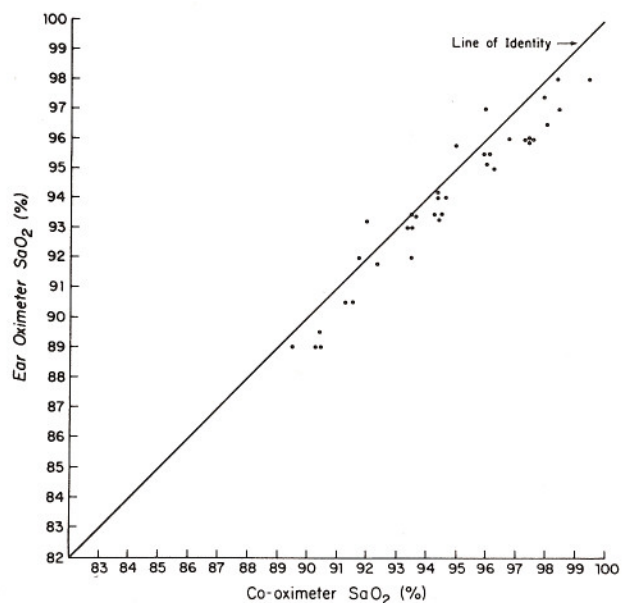


Fig. 7. Oxygen saturation (SaO₂) measurements by both ear oximeter and CO-Oximeter.

boarding at high flows, the benefit ratio of the CNC to SNC decreases as the supply flow increases, although the CNC continues to be an improvement. Thus, curves in the oxygen-delivery model in Figures 2 and 3 are parallel, and our data confirm that fact.

Arterial blood should be analyzed when the CNC is used, as the high oxygen saturation the CNC effects at a low supply flow could result in respiratory-drive depression from oxygen overdosing.

Patient acceptance of the CNC is an issue that has not been investigated in a rigorous fashion. The CNC covers the moustache area of the face and so is more obtrusive,* but the reduction it allows in the size of the oxygen canister source makes it possible for the patient to carry a canister or cylinder rather than pulling it in a cart, which is cumbersome and draws attention to the patient. Some find the appearance of the facial apparatus objectionable, while others feel that the larger cannula is an insignificant factor in the overall appearance of taking oxygen. Almost every patient found the CNC more comfortable; the reservoir is soft and does not cut into the nose or the side of the face. Some patients reported that areas on the face that were chafed from use of an SNC cleared when they began to use the CNC.

In summary, the CNC operates more efficiently than the SNC, achieving adequate oxygen saturation at substantially reduced supply flows. It accomplishes this by storing oxygen during exhalation and releasing it early in the next inhalation, the time of greatest benefit to the patient. Although the CNC is more conspicuous, most patients find it quite comfortable because it is less irritating and its weight is distributed over more of the face. Because the flow of oxygen can be reduced, the CNC can bring about significant financial savings by reducing oxygen usage and making less costly oxygen sources feasible. Also, the portability of the oxygen source can be improved, as smaller oxygen canisters may adequately replace larger ones for the same flow-time requirements.

PRODUCT SOURCES

Oxymizer: Chad Therapeutics Inc, Woodland Hills CA
Biox IIA ear oximeter: Ohmeda (BTI) Boulder CO

*A later model of the Oxymizer has the reservoir in a pendant, lying on the chest, making the cannula less bulky.

CO-Oximeter: Instrumentation Laboratory Inc, Lexington MA
Blood gas analyzers: Instrumentation Laboratory Inc, Lexington MA

Rotometer: Gilmont Inc, Great Neck NY

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Using a Reservoir Nasal Cannula in Acute Care

Cheryl Plate Dumont, RN, MSN, CCRN

Brian L. Tiep, MD

Oxymizer and Oxy-mizer Pendant (CHAD Therapeutics Inc, Chatsworth, Calif) brand reservoir cannulas store oxygen in a reservoir during exhalation and deliver a bolus of 100% oxygen upon the next inhalation. These devices were originally designed for portable home oxygen therapy. However, they are finding increasing use in acute care settings for patients who are difficult to supply oxygen via standard nasal cannulas and as high-delivery alternatives to oxygen delivery via a face mask.¹⁻³

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For example, a reservoir cannula may be used to help prevent reintubation in patients who have chronic lung disease, support oxygenation in patients who are recovering from acute respiratory distress syndrome or have congestive heart failure, and help improve compliance in confused patients who become agitated when a face mask is applied. Understanding the implications of these devices is important to acute care nurses.

In this article, we discuss the implications of oxygen therapy with reservoir cannulas. We include advantages and disadvantages of the cannulas, how these devices operate, their ability to deliver oxygen, possible complications of delivery of high concentrations of oxygen, assessment of pulmonary disease, and a case study.

RESERVOIR CANNULAS

Reservoir cannulas are oxygen-conserving devices. They store 20 mL of oxygen during exhalation and make that oxygen available for the beginning of the next inhalation. They require one half to one fourth the flow rate of standard cannulas at settings of 0.5 to 2 L/min.^{4,7} These devices are available in 2 configurations: the Oxy-mizer and the

Oxy-mizer Pendant.

The Oxy-mizer (Figures 1 and 2) has the reservoir over the mustache area, a location that is more noticeable but is more comfortable for many patients.⁶ The Oxy-mizer Pendant has the reservoir hanging on the anterior chest wall, a less noticeable location. However, the pendant is often less comfortable because of the weight on the ear loops.⁶ Many patients receiving portable oxygen therapy use the Oxy-mizer at home and the Oxy-mizer Pendant to go out of the house. Both devices are disposable and are worn like standard cannulas.⁶

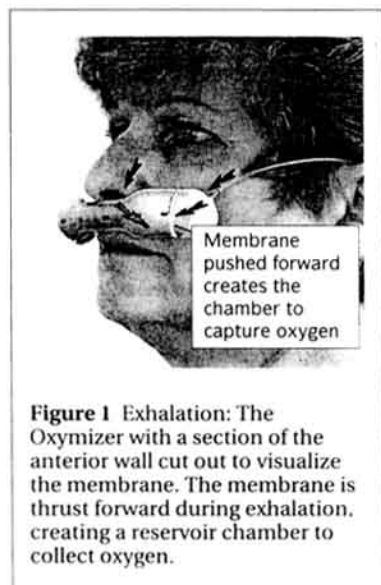


Figure 1 Exhalation: The Oxy-mizer with a section of the anterior wall cut out to visualize the membrane. The membrane is thrust forward during exhalation, creating a reservoir chamber to collect oxygen.

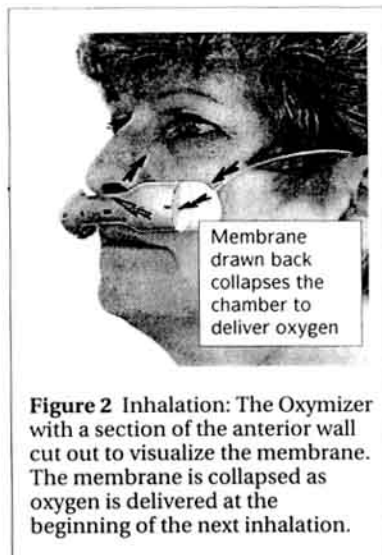


Figure 2 Inhalation: The Oxymizer with a section of the anterior wall cut out to visualize the membrane. The membrane is collapsed as oxygen is delivered at the beginning of the next inhalation.

HOW RESERVOIR CANNULAS WORK

Reservoir cannulas depend on patients' own respiratory effort to cycle and deliver the stored oxygen. The cannula is connected to a source of 100% oxygen in the same way as a standard cannula. As is true of all nasal cannulas, the amount of oxygen actually delivered to a patient's alveoli depends on the oxygen flow rate and the dilution of that oxygen by entrainment of room air. The dilution by entrainment of room air is determined by factors such as mouth breathing, respiratory rate and pattern, inspiratory flow rate, minute ventilation, and altitude.

With a standard cannula, the continuous flow of oxygen during exhalation and during the last part of inhalation is wasted to the atmosphere.^{6,7} Reservoir cannulas are designed to store a bolus of highly concentrated oxygen. This feature helps reduce the effect of dilution by entrained room air at normal inspiratory rates. The reservoir contains a thin membrane that is thrust forward at the

beginning of exhalation, creating a storage chamber between the membrane and the back wall of the reservoir (Figure 1). During the remainder of exhalation, oxygen collects in the chamber. When the patient inhales, the stored oxygen is immediately inhaled in addition to the continuous flow of oxygen (Figure 2). Thus, the patient receives a burst of oxygen at the very beginning of inhalation.^{1,7} This feature concentrates oxygen delivery at the beginning of inhalation, when the delivered oxygen can participate in alveolar capillary gas exchange.

Humidification is not necessary with either standard or reservoir cannulas when low flow rates of 1 to 4 L/min are used. Reservoir cannulas capture exhaled water vapor from patients and return the vapor during inhalation. The vapor is returned at temperatures close to body temperature. Consequently, even without added humidification, reservoir cannulas perform at a higher relative humidity than do standard cannulas. Some clinicians are using added humidification with reservoir cannulas at higher flow rates of 6 to 10 L/min. Contrary to early fears, no condensation and sticking of the membrane inside the reservoir with added humidification have been reported.⁸

OXYGEN DELIVERY

The gas that accumulates in the reservoir of the cannulas is about 80% oxygen at a flow rate of 0.5 L/min and nearly 100% oxygen at a rate of 1 L/min.⁸ As previously noted, the amount of oxygen actually delivered to the alveoli depends on the multiple factors that affect dilution by entrainment of room air.

Tiep et al⁹ developed a theoretical model for predicting oxygen delivery by reservoir cannulas that is based on an inspiratory to expiratory ratio of 1:2, a respiratory rate of 20 breaths/min, and an assumption that the most efficacious delivery occurs in the first 0.5 seconds and the first 200 mL of inhalation. These predictions for oxygen delivery have been validated through laboratory experiments.^{6,8} Studies^{2,4,7} comparing the efficacy of reservoir cannulas with that of standard cannulas consistently indicate that reservoir cannula flow rates of 0.5, 1, and 2 L/min yield a fraction of inspired oxygen (FIO₂) equivalent to that delivered by flow rates of 2, 3, and 4 L/min, respectively, by standard nasal cannulas (Table 1, Figure 3).

Currently, not enough scientific data are available to accurately predict the FIO₂ delivered by reservoir cannulas at high flow rates. Only a single study³ has been done on the use of reservoir cannulas at high flow rates in acute care. Sheehan and O'Donohue³ found that in 9 of 10 patients, reservoir cannula flow rates of 6 to 8 L/min provided arterial oxygen saturation (SaO₂) levels equivalent to the levels provided by an FIO₂ of 0.50 to 0.65 delivered via a face mask.

BENEFITS OF RESERVOIR CANNULAS

The major benefit of reservoir cannulas is their ability to improve the efficiency of oxygen delivery. Patients require one half to one fourth the flow rate of a standard cannula to achieve an equivalent SaO₂.⁸ This increased efficacy enables patients receiving oxygen at home to carry smaller

Table 1 Comparison of oxygen delivery by standard cannula versus reservoir cannula

Parameter	Flow, L/min								
	Air	0.5	1	2	3	4	5	6	7
Fraction of inspired oxygen delivered via									
Standard cannula	0.21	0.23	0.24	0.28	0.31	0.34	0.37	0.41	0.44
Reservoir cannula	0.21	0.29	0.31	0.35	0.38	0.41	0.45	0.48	0.51
Savings ratio	4:1	3:1	2:1	1.7:1	1.5:1	1.4:1	1.3:1	ND	ND
Percent savings	75	67	50	41	35	29	23	ND	ND

*Calculations are based on a respiratory rate of 20 breaths/min and an inspiratory to expiratory ratio of 1:2. Values through 2 L/min have been experimentally confirmed.⁷ ND indicates not determined.

and more portable oxygen containers and to enjoy an extended time away from home, a therapeutic benefit. In addition, fewer deliveries of oxygen containers are needed, a characteristic that reduces the cost of providing oxygen at home.⁸

In acutely ill patients who require an F_{IO_2} of 0.50 or more, reservoir cannulas have 2 major advantages. First, the cannulas facilitate treatment by allowing patients to eat, communicate more effectively, ambulate more easily, and use an incentive spirometer without removing

the oxygen supply. Second, the enhancement in comfort provided by the cannulas and their acceptability increase patients' satisfaction. These factors are important in increasing compliance and decreasing agitation and anxiety. In the home setting, patients sometimes regard a reservoir cannula as more obtrusive than a standard cannula. In contrast, in the acute care setting where patients are using reservoir cannulas as an alternative to face masks, the cannulas are more comfortable and more cosmetically acceptable.^{3,8}

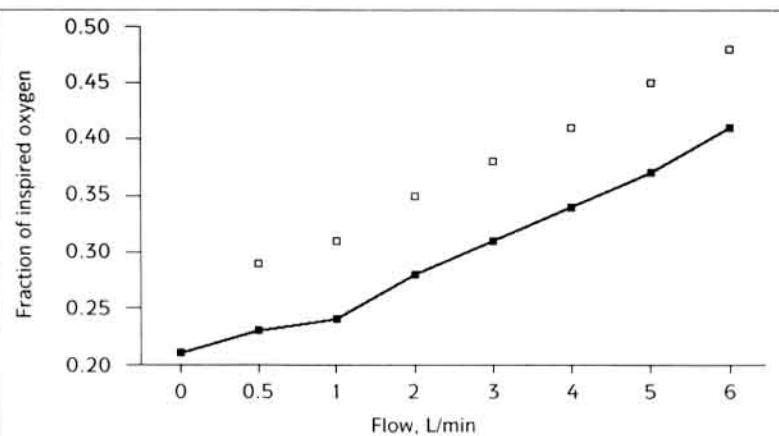


Figure 3 Model of oxygen delivery via a reservoir cannula (open squares) versus continuous flow via a standard nasal cannula (filled squares)⁷

ASSESSING DEGREE OF PULMONARY DISEASE IN RELATION TO OXYGEN REQUIREMENT

When reservoir cannulas are used, patients receive more oxygen than they would receive at the same flow rate from a standard cannula. As a result, patients attain a higher SO_2 with reservoir cannulas than with standard cannulas. However, this increase in SO_2 does not necessarily mean an improvement in pulmonary status. In fact, the complications attributed to high F_{IO_2} values can contribute to a deterioration in status.

Despite the presence of higher than expected SO_2 values, nurses must frequently assess the pulmonary status of patients who are receiving oxygen via reservoir cannulas in the acute care setting. The assessment should include checking for dyspnea, tachypnea, dysphasic respiration, anxiety, restlessness, diaphoresis, tachycardia, and the use of accessory muscles and auscultation of lung fields. Arterial blood gas analysis should be used to determine the adequacy of ventilation and acid-base balance and, if necessary, to measure the degree of intrapulmonary shunt.

Assessing intrapulmonary shunt requires knowledge of the physiology of gas exchange. Shunt refers to a condition in which pulmonary capillary perfusion is normal, but alveolar ventilation and/or diffusion of gases across the alveolocapillary membrane is lacking. In pulmonary shunt, blood flows from the right side of the heart to the left side without being oxygenated. Normally, less than 10% of the cardiac output is shunted. This normal shunt is due to the blood that flows through

the bronchial and thebesian veins. Pathological shunt can be caused by any condition that inhibits the diffusion of oxygen across the alveolocapillary membrane, such as adult respiratory distress syndrome, atelectasis, pneumonia, pulmonary edema, and tumors.

Three methods can be used at the bedside to estimate the degree of shunt: alveolar-arterial gradient ($PAO_2 - PaO_2$; A-a gradient), arterial/alveolar ratio (a/A), and PaO_2/FiO_2 ratio⁹ (Table 2). Measurement of these parameters requires an arterial blood gas analysis and the FiO_2 value. Knowledge of how to use the alveolar gas (PAO_2) equation is also necessary for the first 2 parameters (Table 3).

Assessment of intrapulmonary shunt takes into consideration the partial pressure of oxygen available to the alveoli (PAO_2) and the actual partial pressure of oxygen in the arterial blood (PaO_2). This measurement reflects the effectiveness of oxygen diffusion across the alveolocapillary membrane and therefore gives an estimation of the degree of pulmonary disease. The arterial hemoglobin saturation of oxygen alone, as measured by pulse oximetry (SpO_2) or SaO_2 from the arterial blood gas analysis, does not reveal the degree of intrapulmonary disease. The amount of oxygen required to attain a specific level of oxygenation must be determined.

ADVERSE EFFECTS OF INCREASING FiO_2

Oxygen should be treated as a drug that has potential adverse effects. When reservoir cannulas are used, patients are exposed to higher FiO_2 values than they are when standard cannulas are used.

Table 2 Three methods of assessing intrapulmonary shunt

1. Alveolar-arterial (A-a) gradient = difference between PAO_2 and PaO_2
 Calculated: $PAO_2 - PaO_2$
 Normal: 4 mm Hg PO_2 for each decade of life. Example: In a 50-year-old, the PAO_2 should be no more than 20 mm Hg higher than the PaO_2 .
 Note: This value should be interpreted cautiously because as the fraction of inspired oxygen (FiO_2) increases the A-a gradient widens more and does not necessarily reflect the intrapulmonary process. The A-a gradient is distorted by changes in FiO_2 .
2. Arterial-alveolar (a/A) ratio = ratio of PaO_2 to PAO_2
 Calculated: PaO_2/PAO_2
 Normal: 0.6 to 1
 Note: An a/A ratio less than 0.6 indicates significant intrapulmonary shunt and the need for supplemental oxygen. The a/A ratio is more reliable than the A-a gradient with changes in FiO_2 .
3. PaO_2/FiO_2 = ratio of PaO_2 to FiO_2
 Calculated: PaO_2/FiO_2
 Normal: > 300
 Examples: PaO_2 of 96 mm Hg in a patient on room air with an FiO_2 of 0.21:
 $PaO_2/FiO_2 = 96/0.21 = 457 = \text{normal}$
 PaO_2 of 60 mm Hg in a patient receiving an FiO_2 of 0.60:
 $PaO_2/FiO_2 = 60/0.60 = 100$

Unwanted consequences may include worsening atelectasis from hypoventilation, absorption atelectasis, damage to the lung parenchyma from the toxic effects of oxygen free radicals, and suppression of the hypoxic respiratory drive in patients with chronic carbon dioxide retention.

Absorption atelectasis can be the result of several factors. The atmospheric air is composed of a mixture of gases: 21% oxygen, 79% nitrogen, and trace amounts of carbon dioxide and water vapor. In the alveoli, nitrogen accounts for approximately 74.9%

of the total gas pressure; about 13.6% is due to oxygen, 5.3% to carbon dioxide, and 6.2% to water vapor. Nitrogen is not absorbed into the capillaries and helps splint the alveoli open while oxygen is being absorbed. When 100% oxygen is administered, nitrogen is displaced, leaving the alveoli to collapse as the oxygen is being absorbed.

Cytotoxic effects caused by oxygen-free radicals are a concern with exposure to high concentrations of oxygen. The normal end product of oxygen metabolism is water. In that process, a few

Table 3 Alveolar gas equation

Formula: $PAO_2 = FiO_2 (PB - \text{water vapor}) - (P_{CO_2}/\text{respiratory quotient})$

Components of the formula:

PAO_2 = Partial pressure of oxygen, alveolar

FiO_2 = Fraction of inspired oxygen

PB = Barometric pressure; 760 mm Hg is usually accepted, but the actual PB may be obtained from the pulmonary laboratory

Water vapor pressure in the alveoli = 47 mm Hg (an accepted estimation)

P_{CO_2} = the actual P_{CO_2} value from the patient's arterial blood gas analysis

Respiratory quotient = 0.8 (usually true with a standard mixed diet)

Example: On room air, the FiO_2 is 0.21, and the P_{CO_2} is 40 mm Hg

$PAO_2 = 0.21(760 - 47) - (40/0.8)$

$PAO_2 = 99.7 \text{ mm Hg (which is normal)}$

molecules are partially reduced, creating hydrogen peroxide and other destructive irritants. However, the body compensates and protects itself by producing antioxidants, which neutralize these free

radicals and break them down.

When the concentration of oxygen becomes too great, the concentration of the free radicals also becomes high enough to overwhelm the body's defenses

and cause tissue damage. Alveolar tissue destruction leads to edema, causing shunt. Shunt causes greater hypoxemia, which requires more oxygen. This vicious cycle can be countered by maintaining

CASE STUDY

Ms Estella (a fictitious name) was a 70-year-old woman who underwent emergency coronary artery bypass surgery. Her recovery was complicated by cholecystitis and a cholecystectomy. Weaning from mechanical ventilation was prolonged. After extubation, she continued to require continuous positive airway pressure at night and intermittent positive pressure breathing to keep her oxygen saturation greater than 92%.

Ms Estella was quite anxious and tended to maintain a respiratory rate in the high 20s continually. She was initially given oxygen at a rate of 4 L/min via a standard cannula. During the first 18 hours after extubation, her pulmonary status worsened. She eventually required 50% oxygen via a face mask to maintain her SpO_2 higher than 92%. The face mask contributed to her anxiety and her inability to eat. Boosting her nutritional intake was paramount, because her serum albumin level was 20 g/L. In addition, she could no longer use her incentive spirometer without experiencing oxygen desaturation. Because of these factors, she was treated with a reservoir cannula, initially at a flow rate of 4 L/min, which is equivalent to a flow rate of 6 L/min by a standard cannula. The flow rate was increased during the next 4 hours to 7 L/min (9 L/min by standard cannula) to maintain an SpO_2 of 92%.

With the reservoir cannula, Ms Estella was able to maintain an SpO_2 of 92% even when using her incentive spirometer. During the night, she would fall asleep with the reservoir cannula in place, and her SpO_2 would not decrease. The nightly continuous positive airway pressure was used less often and for shorter periods. However, within 4 days, her respiratory rate elevated into the 30s. She became extremely fatigued. When she was turned to the right side, her SpO_2 plummeted to 80%. The SpO_2 gradually returned to 92% when she was returned to her back or left side. No breath sounds were audible on the left side of her chest.

Arterial blood gas analysis revealed the following: pH 7.45, Pco_2 33 mm Hg, PaO_2 47 mm Hg, and Sao_2 89%. SpO_2 by pulse oximeter was 92%. Although it is difficult to know exactly how much oxygen Ms Estella was receiving, a flow rate of 7 L/min by reservoir cannula is roughly equivalent to a flow rate of 9 L/min by standard cannula. Her FIO_2 can be conservatively estimated to have been 0.50 to 0.60. For an FIO_2 of 0.55, her calculated arterial/alveolar ratio would have been 0.13, which indicates a life-threatening degree of shunt.

An emergent chest radiograph was done and showed consolidation of the entire left lung. Computed tomography of the tho-

rax revealed atelectasis, a pleural effusion, and possible empyema. Ms Estella was reintubated, and a chest tube was inserted. The empyema was too thick to drain through the tube. The following day, Ms Estella was returned to the operating room for the third time in 4 weeks for a thoracotomy and wedge resection.

Use of the reservoir cannula was a good choice for Ms Estella. She was much more comfortable with it than with a face mask, and she was able to eat until her fatigue and dyspnea interfered. However, the ability to maintain an SpO_2 of 92% with the reservoir cannula may have imparted a false sense of security. The vigilance and therapy regimens were relaxed, and the pulmonary process worsened without being recognized. To counter such possibilities, clinicians must remain vigilant and closely monitor respiratory status. If Ms Estella had been using a nonre-breather mask, most likely the healthcare staff would have aware of the change in her status. The sight of these large masks with a reservoir bag communicates instantly that a patient is having severe gas exchange problems and alerts staff that diligent pulmonary therapy is warranted. In addition, the results of pulse oximetry should be corroborated with the results of arterial blood gas analysis to ensure that the Sao_2 values are accurate.

oxygen administration at the lowest adequate level and by addressing lung pathophysiological changes.

Elevated PaCO_2 is normally the primary stimulus for respiration. Patients with chronically elevated levels adapt to the elevation, and PaCO_2 becomes a very weak stimulus for respiration. In these patients, PaO_2 becomes a more important stimulus for respiration. However, PaO_2 has essentially no effect on respiration until it decreases to less than 100 mm Hg. At a PaO_2 of 60 mm Hg, respiratory effort doubles. Supplemental oxygen in patients with chronically elevated PaCO_2 sometimes causes suppression of respiratory effort. This fact in no way means that oxygen should be withheld from patients who need it. It simply means this danger should be recognized and that patients should be monitored and assisted ventilation used when appropriate.

Increasing the FiO_2 is often necessary to maintain oxygenation and prevent tissue hypoxia. Many patients with pulmonary disease respond well to increased oxygen delivery, even high concentrations for a short time. Patients with intrapulmonary shunting have less significant improvement with increased FiO_2 . These patients require bronchial hygiene, bronchodilators, diuretics, positive-pressure ventilation, and sometimes anti-inflammatory agents to treat the underlying illness. When increasing a patient's FiO_2 , clinicians should be aware of potential complications and should monitor the patient more frequently and use therapies to prevent and correct atelectasis.

The case study (shaded box) illustrates the vigilance required

for patients using reservoir cannulas at high flow rates.

CONCLUSION

Some anecdotal evidence¹ indicates that the FiO_2 delivered by reservoir cannulas at flow rates greater than 2 L/min may be higher than predicted by calculations. Currently, there is no way to prove or disprove this possibility. We recommend that reservoir cannulas be compared with face masks and continuous flow via standard cannulas to determine FiO_2 equivalencies at higher flow rates.

Reservoir cannulas can be a valuable adjunct in the acute care setting. They should be used judiciously as an alternative to a face mask in patients who have refractory hypoxemia and require 50% or more oxygen. However, staff must be alert to the presence and severity of intrapulmonary disease that would require an FiO_2 greater than 0.50. Any time a patient using a reservoir cannula requires a flow rate greater than 4 L/min, severe pulmonary disease must be suspected, and appropriate evaluation, monitoring, and therapies must be instituted. †

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A New Pendant Storage Oxygen-conserving Nasal Cannula*

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With increasing interest in reducing the cost of oxygen therapy, we recently designed an oxygen-conserving cannula. It reduces the oxygen supply flow necessary to achieve adequate oxygen saturation, but because it requires the use of a reservoir situated under the nose, some patients find it obtrusive. We therefore designed a similar system but displaced the reservoir away from the face and onto the anterior chest wall where it could be hidden from view by the patient's clothing. We evaluated this pendant conserving nasal cannula (PNC) in seven hypoxemic patients with chronic obstructive pulmonary disease. We compared oxygen saturations achieved using the PNC vs the standard

It is now established that low flow oxygen therapy is beneficial to hypoxemic patients with chronic obstructive pulmonary disease (COPD). The Nocturnal Oxygen Therapy Trial,¹ British,² and other studies³⁻⁵ have demonstrated that such low oxygen given between 12 and 24 hours daily improves survival, reduces pulmonary hypertension, improves cor pulmonale, reduces polycythemia, improves psychomotor skills, and reduces depression. Oxygen is generally administered via a nasal cannula flowing continuously throughout the respiratory cycle. However, the greatest benefit of oxygen therapy occurs during early inspiration with much of the remaining oxygen lost to the surrounding environment.

There has been some recent interest in improving the efficiency of oxygen delivery by a redesign of the oxygen cannula. We recently described an oxygen-conserving nasal cannula with a storage reservoir over the mustache area of the face.^{6,7} The goal of this device was to increase the proportion of oxygen flow during early inspiration and thereby achieve adequate saturations with a reduction in total oxygen delivered. At flows of 0.5 L/min to the conserver cannula, the benefit was nearly that achieved at 2 L/min using the steady flow cannula. One difficulty with prescribing oxygen is patient acceptance. While the conserver can reduce to one third to one half the present cost of oxygen, some patients found the reservoir over the mustache area

steady flow nasal cannula (SNC) at 0.5 through 4 L/min. The mean improvement in oxygen saturation using the PNC vs the SNC was 3.3 percent at 0.5 L/min, 4.3 percent at 1 L/min and 3.1 percent at 2 L/min. These differences were statistically significant ($p < 0.001$). The saturation achieved by the PNC at 0.5 L/min was equivalent to that achieved by the SNC at 1.8 L/min. We conclude that the PNC provides effective oxygen delivery to patients at supply flows substantially less than the SNC. The device is aesthetically acceptable to patients and its widespread use in patients requiring chronic oxygen therapy could bring about significant financial savings.

more obtrusive than standard cannulas. In an effort to reduce the relative size of the cannula at the front of the face, we have redesigned the conserver cannula by displacing the storage reservoir off the face. In this design, the storage reservoir resides in a pendant which hangs below the neck on the anterior chest where it can be hidden under the clothing. In this study, we evaluated the efficacy of the pendant conserver cannula by comparing it to the standard steady flow cannula at various oxygen supply flows using oxygen saturation measured via ear oximetry.

METHODS

Pendant Conserver Cannula

Figure 1 shows the pendant conserver cannula. It consists of nasal prongs attached to tubular conduit leading to the oxygen reservoir. The oxygen flows to the juncture of the conduit and reservoir bag. The bag stores 40 mL of gas and is available for oxygen enrichment. The tubing also provides some storage. Like the previously described conserver cannulas,^{6,7} the patient must do some nasal breathing during inspiration and expiration in order to derive added benefit from oxygen stored in the reservoir. The pendant conserver stores oxygen during exhalation; during early exhalation, the increase in nasal pressure forces oxygen into the reservoir. When the reservoir is filled, oxygen fills the conduit (20 mL) leading to the patient. The effect is that oxygen enriched gas is poised for early inhalation.

Protocol

We recruited seven patients with stable chronic lung disease with a mean age of 55.6 ± 14.6 years and a mean FEV₁ of 0.72 ± 4 L for this study. All subjects either had a resting oxygen saturation of 90 percent or less or desaturated to less than 90 percent during low level exercise. They were allowed to continue their medications except they could not receive inhaled bronchodilators within one hour prior to the study. Each subject gave informed consent to participate in the study. Oxygen saturation was measured by means of an ear oximeter.

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FIGURE 1. The pendant oxygen conserving nasal cannula showing the nasal prongs, storage/reflux conduit, and reservoir.

and oxygen flow was metered via a spirometrically calibrated Gilmont rotometer accurate to ± 0.05 L/min. The study was performed with the subjects in a comfortable upright seated position. We measured oxygen saturations at room air, 0.5, 1.0, 2.0, 3.0 and 4.0 L/min using the standard steady flow nasal cannula and at 0.5, 1.0 and 2 L/min using the pendant conserver cannula. The order of presentation of cannulas was randomized, but all measurements started with lowest flow progressing to the highest flow. They were allowed to return to baseline by breathing room air between cannula changes. We determined the time required for saturation equilibration to occur and added two minutes to each oxygen flow level prior to recording saturation in an effort to assure that equilibration had taken place. We compared the mean saturations for each cannula at .5, 1, and 2 L/min using an analysis of variance.

Table 1—Oxygen Saturations Achieved by the Pendant Conserving Nasal Cannula vs the Steady-Flow Cannula

	Patient No.							Mean O ₂ Saturation
	1	2	3	4	5	6	7	
SNC*								
0.5	93	92	86.5	86	88.5	92	92	90 ± 2.9
1.0	93.5	94	86.5	87	91	93	93	93 ± 3.1
2.0	95	94.5	92	94.5	95	95	93	93 ± 1.3
3.0	96	96	94	96	97	96	94	95 ± 1.1
4.0	97	97	97	97.5	96	96	95	96 $\pm .8$
PCC†								
0.5	94.5	96	88	92	94	95.5	93	93.3 ± 2.7
1.0	96	97	90.5	96	96	97.5	94	95.3 ± 2.4
2.0	97	97	96	97	97	99	95	96.8 ± 1.2

*Steady-flow nasal cannula.

†Pendant conserver cannula.

RESULTS

Table 1 summarizes the observed oxygen saturations achieved by each patient using the standard steady flow cannula and the pendant conserver cannula at various supply flows. The mean room air saturation was 88.4 ± 2.8 percent. The mean saturation at .5 L/min was 90 ± 2.9 percent for the standard cannula and 93.3 ± 2.7 percent for the pendant conserver. At 1 L/min, the mean saturation was 91 ± 3.1 percent for the standard cannula and 95.3 ± 2.4 percent for the pendant conserver. At 2 L/min, the saturation was 93.7 ± 1.3 percent for the standard cannula and 96.8 ± 1.2 percent for the pendant conserver. These differences in oxygen saturations between the two cannulas were found to be statistically significant ($p < 0.001$) by analysis of variance. Figure 2 compares the oxygen saturations achieved by using the standard cannula and pendant conserver for each subject at 0.5, 1.0, and 2 L/min. The first point in each panel represents the standard cannula, and the second point represents the pendant conserver at each supply flow. In each instance, the pendant conserver yields a higher saturation compared to the steady flow cannula. Figure 3 represents the oxygen saturation performance curves for the standard steady flow cannula and the pendant conserver. At 0.5 L/min, the benefit of supplemental oxygen via the pendant conserver is equivalent to that achieved from 1.85 L/min using the standard steady-flow cannula. This provides a benefit ratio of 3.7:1. At 1 L/min of oxygen delivered to the pendant conserver, the mean saturation is equivalent to the standard steady-flow cannula at 2.8 L/min, yielding a benefit ratio of 2.8:1. At 2 L/min flow to the pendant conserver cannula, the mean oxygen saturation is equivalent to

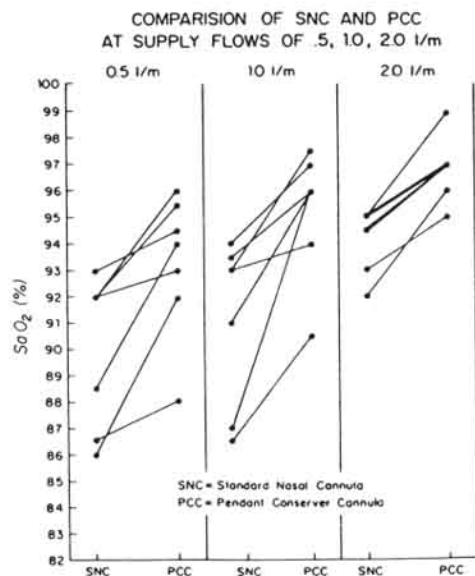


FIGURE 2. Comparison of SNC and PCC at supply flows of .5, 1.0, 2.0 L/min.

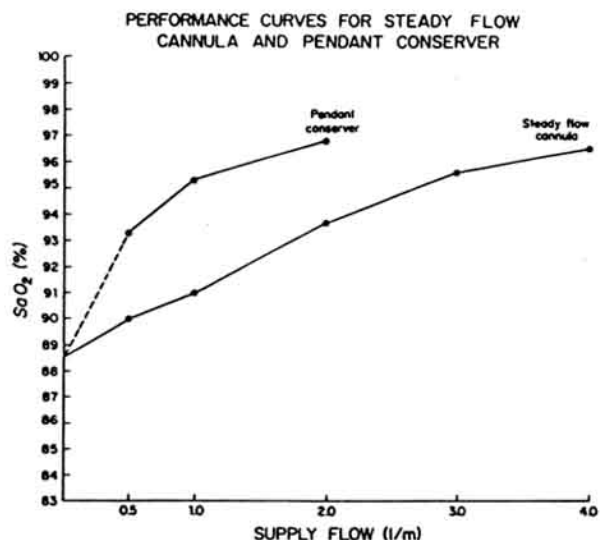


FIGURE 3. Performance curves for steady flow cannula and pendant conserver.

that of 4 L/min for the standard steady flow cannula yielding a benefit ratio of 2:1.

DISCUSSION

We found that the pendant conserver achieved significantly better saturations than the standard steady flow cannula at the same supply flows (Fig 3). The error stated by the manufacturer of the ear oximeter is ± 1.7 percent at saturations of 90 to 100 percent. Notwithstanding this range of error, this study is significant. These results are expected since exhalation occupies 60 to 70 percent of the respiratory cycle. In addition, during the last 30 to 40 percent of inhalation, gas flows principally to dead space. Therefore, gas exchange occurs primarily in the first 20 to 30 percent of the respiratory cycle. The pendant conserver stores a bolus of oxygen during exhalation making it available for early inspiration. In addition to this stored bolus, the pendant conserver operates as a steady flow cannula.

The goal of oxygen therapy is to prevent tissue hypoxia. The usual steady flow prescription is 2 L/min with adjustments for sleep and exercise.^{8,9} If the pendant conserver cannula provides adequate saturations at lower supply flows, substantial financial savings could be achieved. This is particularly useful to patients requiring ambulatory oxygen.

Our previous studies described a similar benefit using a storage cannula with a reservoir residing in the mustache area of the face.^{6,7} While both efficacy and

comfort were improved, some patients found it obtrusive. Therefore, it became apparent that there would be some advantage to removing the reservoir from the face and hanging it around the neck like a pendant. The reservoir could then be hidden by clothing, thereby diminishing its obtrusiveness while retaining the value of its storage capabilities. Subjects were asked to comment about the comfort and appearance of the pendant conserver. Most subjects report that the pendant conserver is more comfortable than the standard steady flow cannula and felt it to be less obtrusive than the presently marketed mustache conserver. Both the pendant and mustache conservers could diminish the obtrusiveness of the oxygen cannister by reducing the storage requirement, thus making smaller and lighter oxygen containers more feasible.

In conclusion, the pendant oxygen conserving cannula provides effective oxygen delivery at substantially reduced oxygen supply flows as compared to the standard steady flow cannula. Because of this improved efficacy, the pendant conserver could significantly reduce the cost of oxygen therapy. It is more comfortable than the standard steady flow cannula. Furthermore, the fact that the reservoir is hidden from view makes the system aesthetically more acceptable than the mustache configured conserver.

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Evaluation of a Low-Flow Oxygen-Conserving Nasal Cannula^{1,2}

Low-flow continuous oxygen is an accepted form of therapy in patients with chronic obstructive lung disease (COPD) with hypoxia (1-5). An increasing number of patients are prescribed oxygen for chronic use. The drawbacks of portable oxygen are its inconvenience and cost.

Supplemental oxygen is commonly delivered by means of a nasal cannula through which the oxygen flows continuously. The greatest benefit of oxygen to the patient occurs during early (nondead space) inspiration. Thereafter, most of the remaining oxygen is lost to the atmosphere. It would, therefore, be desirable to concentrate oxygen delivery in the initial phase of inspiration.

An oxygen cannula was developed that contains a closely coupled reservoir that stores oxygen on exhalation to be delivered during early inhalation (Oxymizer; Chad Therapeutics, Inc., Woodland Hills, CA). The goal of the device is to reduce the oxygen flow and still achieve adequate oxygen saturation. This study evaluated patients from 2 hospitals to compare oxygen saturation achieved using the new conserver cannula versus the standard steady flow cannula.

The oxygen conserver cannula, as shown in figure 1, consists of nasal prongs, an attached, closely coupled, 20-ml reservoir with a collapsible membrane, and an oxygen supply line at the distal end of the reservoir on each side (6). The cannula with its reservoir covers the face in a mustache distribution extending out to the cheeks. The oxygen tubing extends laterally from the reservoir over the ears and merges into a single supply tube similar to most standard cannulas. In order to operate the conserver cannula, the patient must do at least some nasal breathing. The conserver cannula stores oxygen in the following manner: during the early portion of exhalation, the dead space gas pushes the membrane out filling the cannula reservoir. After the reservoir is filled and during the remaining portion of exhalation, oxygen displaces the original dead space gas medially by venting it through the nasal prongs. During early inspiration, the patient

SUMMARY Oxygen therapy is one of the most frequently ordered therapies for patients with chronic obstructive pulmonary disease (COPD). In a large percentage of these cases, oxygen therapy is supplied via nasal cannula. With the rising cost of medical care and the search for more effective means of oxygen delivery, a new oxygen-conserving nasal cannula (CNC) that incorporates a closely coupled 20-ml reservoir was developed. Oxygen is stored in the reservoir during exhalation so that 20 ml of approximately 85% oxygen is the first gas inhaled. To test the hypothesis that the CNC is more efficient than the standard nasal cannula (SNC), 20 patients with COPD were evaluated. All patients were chronically hypoxemic at rest. Results indicate that when the CNC was compared with the SNC, arterial oxygen saturation levels were significantly different ($p < 0.001$) at flow rates of 0.5, 1.0, and 2.0 L/min. Oxygen saturations were 2.9% higher at 0.5 L/min, 2.9% higher at 1 L/min, and 2.6% higher at 2 L/min for the CNC than for the SNC. In summary, the CNC offers a more efficient oxygen delivery system for those patients requiring supplemental oxygen administration by nasal cannula.

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inhales the 20-ml bolus of approximately 85% oxygen from the reservoir, thus collapsing its membrane.

Twenty patients with stable COPD, and with a mean age of 64.8 yr, volunteered for this study. As shown in table 1, all patients had severe COPD with a mean forced expiratory volume in one second of 0.76. Subjects were allowed to continue their medication schedule, except that inhaled bronchodilators were withheld for at least 1 h prior to the study. All subjects signed an informed consent, in compliance with the policy of the Institutional Review Boards of the 2 institutions. Each subject met the following criteria: (1) severe chronic lung disease, (2) resting hypoxemia with an oxygen saturation less than 90%, and (3) no significant bronchospasm at the time of study. Oxygen saturation was measured using the Biox 11A ear oximeter (Biox Technology, Inc., Boulder, CO), and recorded on a strip-chart recorder. Oxygen supply flow was metered via spirometrically calibrated Gilmont rotometer (Gilmont Inc., Great Neck, NY), which could be adjusted within ± 0.05 L/min. Subjects were all studied in an upright, comfortably seated, position.

Saturation measurements were made at 0.5, 1, 2, 3, and 4 L/min using the standard nasal cannula, and at 0.5, 1, 1.5, and 2 L/min using the conserver cannula. The subjects were allowed to return to their room air saturation level between cannula changes. The choice of cannulas was ran-

domized, but flow rates started with the lowest value and increased incrementally. Equilibration time was determined by allowing oxygen saturation to stabilize; after stabilization, an additional 2 min of data were recorded to assure that equilibration had occurred. Final oxygen saturation values were used in the data analysis. Statistical comparisons were made using analysis of variance, followed by the Duncan's multiple-comparison technique.

Oxygen saturation for each level of oxygen flow for all subjects can be seen in table 2. The mean room air SaO_2 was 88% with both the standard and conserver cannulas in place. The mean room air SaO_2 improved with either cannula. At flows of 0.5 and 1 L/min, the oxygen saturation was 2.9% greater with

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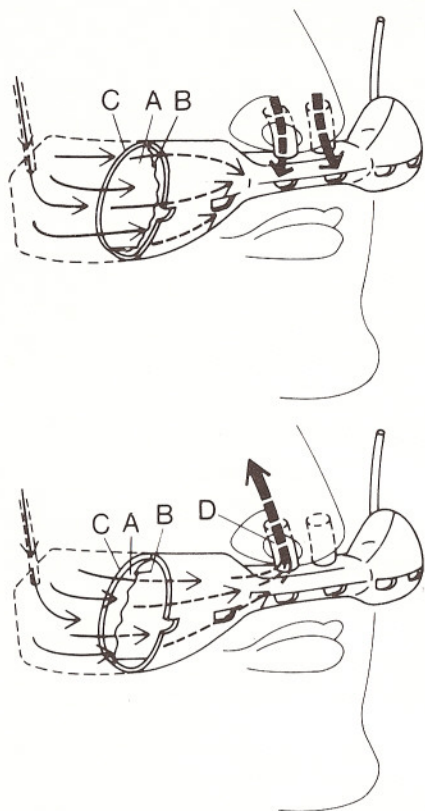


Fig. 1. While the patient is exhaling (top), oxygen is accumulating in the reservoir (A) formed by the inflated diaphragm (B) and the back wall of the conserver (C). While the patient inhales (bottom), the diaphragm (B) collapses, and the oxygen-enriched gas from the reservoir (A) is released to the patient (D).

the conserver than with the standard cannula. At 2 L/min the saturation was 2.6% higher with the conserver. These differences were significant ($p < 0.001$). The results obtained at the 2 centers showed no significant differences. Oxygen saturations with the conserver and with the standard cannula for each subject at supply flows of 0.5, 1, and 2 L/min are shown in figure 2. It is apparent that the conserver cannula improves SA_{O_2} for similar supply flows.

A comparison of oxygen saturation curves for both the standard cannula and the conserver can be seen in figure 3. Plotted are mean values at each flow for all subjects. When the supply flow to the conserver cannula is set at 0.5 L/min, the oxygen saturation is equivalent to that achieved by the standard cannula set at 1.8 L/min. When the supply flow to the conserver is set at 2 L/min, the saturation is equivalent to that achieved by the standard cannula set in excess of 4 L/min. The mean benefit ratio of the conserver to the standard cannula, when set at 0.5 L/min, is 3.6:1 (with a range of 2:1 to 6:1). However, the mean benefit ratio reduces to 2:1 (with a range of 1.8:1 to 3:1) as the supply flow to the conserver cannula approaches 2 L/min.

* * *

This study demonstrated that essentially the same arterial oxygen saturation values can be obtained at reduced flow rates when using the conserver nasal cannula as when using the standard cannula. This phenomenon should not be surprising if one critically evaluates the principles of operation of both cannulas along with the mechanics of breathing.

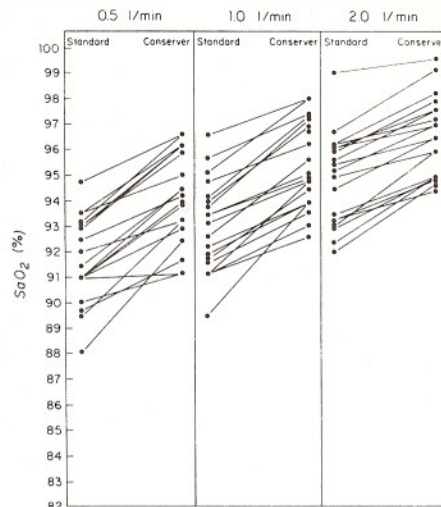


Fig. 2. The conserver is compared with the standard (steady-flow) cannula at 0.5, 1, and 2 L/min. At each supply flow the conserver achieves significant improvement in oxygen saturation (SA_{O_2}) over the standard cannula ($p < 0.001$).

The standard nasal cannula is designed to provide flow rates of 0.5 to 6.0 L/min. Estimates for fraction of inspired oxygen (FI_{O_2}) range from 24 to 44% at flows of 1 to 6 L/min, respectively. During a normal respiratory cycle, 60 to 70% of the time is expended for the expiratory process; thus, only 30 to 40% of the available flow occurs during inhalation. Further, the presence of a 150-ml dead space with a 450-ml tidal volume reduces available supply still further. In contrast, the conserver cannula design permits approximately 20 ml of oxygen to become trapped during expiration; thus, the oxygen is available as a bolus during the first phase of inspiration. This mechanism amplifies the benefit of oxygen administration by providing a greater concentration of oxygen early in the inspiratory phase, thus providing a higher FI_{O_2} at the alveolar level. Once the bolus is delivered, the cannula performs similarly to the stan-

TABLE 1
DEMOGRAPHIC AND PULMONARY FUNCTION DATA

	Number	Males (n)	Age (yr)	FVC (L)	FEV ₁ (L)	FEV ₁ /FVC (%)
COH	10	6	66.7 ± 5.2	2.30 ± 0.70	0.66 ± 0.18	28.7 ± 2.4
UTHCT	10	7	62.9 ± 9.0	2.02 ± 0.68	0.85 ± 0.39	42.1 ± 5.7
Total	20	13	64.8 ± 7.1	2.16 ± 0.69	0.76 ± 0.29	35.4 ± 4.1

Definition of abbreviations: FVC = forced vital capacity; FEV₁, forced expiratory volume in one second; COH = City of Hope National Medical Center; UTHCT = University of Texas Health Center at Tyler.

TABLE 2
MEAN OXYGEN SATURATIONS ACHIEVED BY THE CONSERVER NASAL CANNULA VERSUS THE STEADY FLOW CANNULA

	Administered O ₂ Using Nasal Cannula (L/min)						
	Room Air	0.5	1	1.5*	2	3†	4†
Standard cannula							
Mean O ₂ saturation, %	88.3	90.3	91.6	—	93.6	95.1	96.1
SD	6.8	6.3	6.3	—	5.7	3.6	2.7
Conserver cannula							
Mean O ₂ saturation, %	88.0	93.2	94.5	95.4	96.2	—	—
SD	6.9	5.8	4.1	2.9	2.3	—	—
Difference in O ₂ saturation between standard and conserver cannula, %	0.3	2.9	2.9	—	2.6	—	—

* Saturations were measured at 1.5 L/min only while using the conserver.

† Target saturations were achieved by the conserver at 2 L/min; therefore, measurements were not taken at 3 and 4 L/min.

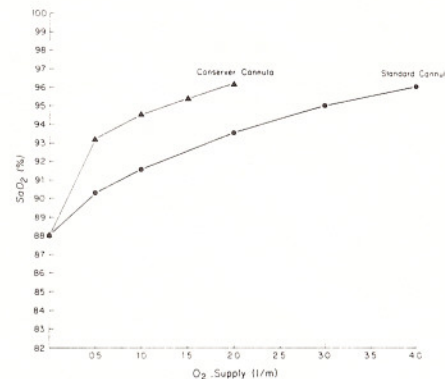


Fig. 3. Oxygen saturation (SA_{O_2}) is shown for the conserver and for the standard (steady-flow) cannula at supply flows from 0.5 to 4 L/min. At 0.5 L/min, the conserver provides an equivalent saturation to the standard cannula at 1.8 L/min. At 2 L/min, the conserver provides the equivalent to 4 L/min via the standard cannula.

standard cannula by providing additional oxygen through constant flow. The most common level of oxygen prescribed is 2 L/min (7,8). If adequate oxygen saturation could be achieved with a conserver cannula at supply flows of 0.5 or 1.0 L/min, the financial savings could be substantial, particularly in portable oxygen. The sources of savings would be (1) reduction of oxygen supply consumption, (2) reduction in home tank deliveries, and (3) the potential to use less costly portable compressed gas transfill systems as an alternative to more expensive liquid systems. In addition, the conserver would allow an increasing time away from the mother reservoir while using portable transfill oxygen systems.

Subjects were questioned as to the comfort of the conserver. Most subjects found it quite comfortable because the cannula weight was distributed over a larger portion of the face and the prongs were not as sharp as those on their present cannula. Responses to the appearance of the conserver varied; patient acceptability is a question that will remain for future studies.

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The writers wish to thank Robert Phillips and Ben Otsap for their help in the development of the conserver cannula and Chad Therapeutics, Inc., for their support of our research.

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A M E R I C A N C O L L E G E O F



P H Y S I C I A N S[®]

Conservation of Oxygen Supply Using a Reservoir Nasal Cannula in Hypoxemic Patients at Rest and during Exercise*

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A reservoir nasal cannula which stores oxygen during exhalation and delivers it as a bolus during inhalation has been reported to conserve oxygen delivery in patients with chronic obstructive pulmonary disease (COPD) at rest. We compared the effects upon arterial oxygen saturation (SaO_2) of the reservoir cannula and a standard nasal cannula in hypoxemic obstructed and restricted patients at rest and during exercise. The SaO_2 was monitored by ear oximeter. While at rest, 13 obstructed and four restricted patients breathed oxygen from the reservoir cannula at 0.5, 1.0, 1.5, and 2.0 L/min and from a standard cannula at 0.5, 1.0, 2.0, 3.0, and 4.0 L/min. Mean SaO_2 was significantly higher with the reservoir cannula compared to the standard cannula at 1.0 and 2.0 L/min ($p < 0.0006$) and tended to be higher at 0.5 L/min ($p < 0.1$). Seven obstructed patients walked on a level

treadmill at 0.75 mph while breathing oxygen at 0.5 and 1.5 L/min from the reservoir cannula and at 1.0 and 3.0 L/min from the standard cannula. The SaO_2 during exercise with the reservoir cannula was comparable to that with the standard cannula at approximately half of the oxygen flow rate. The ratio of the oxygen flow rate of the standard to the reservoir cannula to produce 90 percent saturation was estimated and found to be 2.5 ± 0.8 (mean \pm SD) for patients at rest and 2.9 ± 1.8 during exercise. We conclude that in hypoxemic patients at rest and during exercise, the reservoir cannula uses less than half the oxygen of a standard cannula to produce similar improvement in SaO_2 , and thus has advantages of a reduced cost of ambulatory therapy with low-flow oxygen and a longer time permitted away from a stationary source of oxygen.

Because supplemental oxygen improves survival in hypoxemic patients with chronic obstructive pulmonary disease (COPD) and presumably in patients with chronic restrictive disease, delivery of oxygen to the hypoxemic patient by nasal cannula is an established mode of therapy. Despite the acknowledged efficacy, there is concern regarding the cost of this treatment. Moreover, the limited duration of oxygen supply from portable sources poses an inconvenience to ambulatory patients.

Delivery of oxygen by nasal cannula is inherently inefficient due to the oxygen escaping into the atmosphere during exhalation. Several devices are in development or are being marketed to improve the oxygen efficiency of the nasal cannula. In this study, we tested a widely marketed, simple-to-operate example of these devices, a nasal cannula with a built-in reservoir

(Oxymizer, Chad Therapeutics, Inc). This cannula stores oxygen during exhalation, delivering the stored oxygen as a bolus during inhalation.¹ We tested this device in patients with hypoxemic pulmonary disease at rest and with ambulation to determine its efficiency and oxygen-conserving ability compared with the standard nasal cannula.

MATERIALS AND METHODS

Twenty subjects were selected from patients cared for in the Pulmonary Divisions of the UCLA Medical Center, Los Angeles, and the Veterans Administration Hospital, Sepulveda, Calif. Subjects were selected for study if they had stable chronic obstructive or restrictive ventilatory disease and were already receiving long-term therapy with low-flow oxygen or were being evaluated for the first time for supplemental oxygen therapy at home. Subjects were further screened for inclusion in the study by ear oximeter (Biox Technology model II-A). The criterion for selection was arterial oxygen saturation (SaO_2) of 90 percent or less while breathing room air. Subjects signed an informed consent approved by the human subjects' protection committee at the institution where the study was performed.

All subjects underwent routine spirometric testing using a rolling-seal spirometer (Cardio-Pulmonary Instruments model 220) and measurement of arterial blood gas levels. Determination of blood gas levels was in duplicate using a semiautomated blood gas analyzer (Corning Medical model 168). The SaO_2 and carboxyhemoglobin saturation of arterial blood were determined with a spectrophotometric oximeter (CO-Oximeter model IL287; Instrumentation Laboratory, Inc). Wherever possible, arterial blood was sampled simultaneously with an ear oximeter. Subjects then underwent studies with a nasal cannula as described subsequently.

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Each subject was studied at rest with both a standard nasal cannula (Salter Labs model 1600) and a reservoir nasal cannula applied in random order. An ear oximeter was used to monitor arterial oxyhemoglobin saturation while air at 1.0 L/min and oxygen at 0.5 (in only four obstructed and three restricted subjects), 1.0, 2.0, 3.0, and 4.0 L/min were delivered to the standard nasal cannula or air at 1.0 L/min and oxygen at 0.5, 1.0, 1.5, and 2.0 L/min were delivered to the reservoir cannula. The patients breathed oxygen at each flow rate for at least five minutes, and arterial saturation was recorded after it had achieved a stable value for an additional two minutes. When all measurements were completed with one type of cannula, the procedure was repeated with the other type of cannula, starting with air and followed by the breathing of oxygen at the flow rates in the sequence indicated previously. Subjects were observed continuously to monitor respiratory rate and to ascertain whether breathing was through the nose, mouth, or both. The respiratory rate and predominant mode of breathing were recorded for each oxygen flow rate tested.

The seven obstructed patients studied at the UCLA Medical Center were selected to determine if the reservoir cannula would conserve oxygen during exercise. The subjects were screened by ear oximeter while walking to ensure that their SaO₂ on room air remained at 90 percent or less with exercise. These subjects were studied during exercise while breathing supplemental oxygen at 0.5 and 1.5 L/min via the reservoir cannula and at 1 and 3 L/min via the standard cannula. The studies were carried out at the same session as the resting protocol, which was modified in the following way. After subjects had reached a steady state at rest breathing oxygen at 0.5 or 1.5 L/min via the reservoir nasal cannula and at 1 and 3 L/min via the standard nasal cannula, they walked on a level treadmill at 0.75 mph for a target duration of five minutes while continuing to inspire supplemental oxygen at the same flow rate via the same cannula that they used during the preceding resting period. Two subjects were unable to walk for the full five minutes but walked for at least three minutes during all exercise periods. Respiratory frequency was counted, and the pattern of breathing (nose, mouth, or both) was noted during the last 30 seconds of exercise. Following each exercise period, subjects were switched to the next higher flow rate of oxygen indicated by the resting protocol and rested (generally for more than ten minutes) until a new steady level of SaO₂ was achieved.

Statistical analyses were performed separately in subjects with obstructive and restrictive ventilatory impairment. A two-way analysis of variance by subject and type of cannula was used to determine if significant differences existed in each group of subjects between the SaO₂ achieved with the two types of nasal cannulae delivering the same flow rate of oxygen.

A similar analysis was used to determine if SaO₂ at twice the oxygen flow rate with the standard cannula was different compared to the reservoir cannula. An oxygen conservation ratio at 90 percent saturation and the percentage of savings in oxygen supply required to achieve 90 percent saturation were calculated to quantitatively estimate the oxygen-sparing capabilities of the reservoir cannula compared to the standard cannula. The conservation ratio at 90 percent saturation was defined as the flow rate for the standard cannula divided by the flow rate for the reservoir-type cannula required to achieve 90 percent saturation. The flow rate of oxygen required to achieve an SaO₂ of 90 percent was estimated for each type of cannula by linear interpolation of the data. The method of calculating the conservation ratio for subject 4 with COPD is shown in Figure 1. The percentage of savings in oxygen supply was determined by subtracting the reciprocal of the concentration ratio from one and multiplying by 100. Student's *t*-test was used to determine the significance of the difference in the percent savings in oxygen supply from zero. Least-squares linear regression was used for all subjects combined to test the correlation between arterial saturation measured by ear oximeter and spectrophotometric oximeter and the correlation between conservation ratio or percentage of savings in oxygen supply and respiratory rate.

RESULTS

Table 1 lists the subjects' baseline characteristics. Oxyhemoglobin and carboxyhemoglobin saturations by spectrophotometric oximeter were not obtained in subjects 4 and 11. Subjects 1, 3, and 18 to 20 had an SaO₂ of 90 percent or less at the time of screening but were later found to have an SaO₂ of more than 90 percent by oximeter on the day of the study. Subjects 1 and 3 with SaO₂ above 90 percent by ear oximeter had spectrophotometric oximetric data indicating an SaO₂ of 90 percent or less. These subjects were included in the resting studies. Subjects 18 to 20 were studied during exercise but not at rest because they had sufficient desaturation only during exercise to meet the criterion of an SaO₂ of 90 percent or less on room air. Four patients had carboxyhemoglobin values that were significantly elevated, presumably due to cigarette smoking prior to the study. The mean intraindividual difference between SaO₂ determined by ear oximeter and the spectrophotometric oximeter (0.5 ± 2.6 percent) was not significantly different from zero. Linear

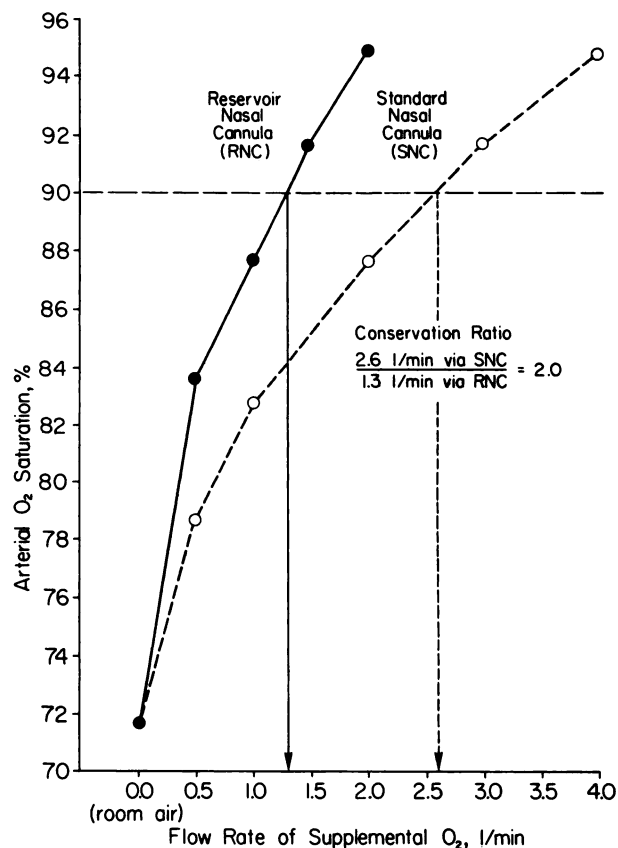


FIGURE 1. Method of calculating oxygen conservation ratio. Ear oximetric SaO₂ was determined at indicated oxygen flow rates through reservoir nasal cannula and standard nasal cannula. Oxygen flow rate to produce 90 percent saturation is determined by linear interpolation between two oxygen flow rates that most closely bracket 90 percent saturation. Oxygen conservation ratio is then calculated by dividing oxygen flow rate of standard nasal cannula by oxygen flow rate of reservoir cannula corresponding to 90 percent saturation. Oxygen conservation ratio in this obstructed patient is 2.0 (case 4).

Table 1—Data on Pulmonary Function and Blood Gas Levels

Group and Case, Sex, Age (yr)*	Diagnosis†	FVC, L (percent of predicted)	FEV ₁ , L (percent of predicted)	FEV ₁ /FVC, percent	Resting Arterial Blood Gas Levels‡					
					pH	PaCO ₂ , mm Hg	PaO ₂ , mm Hg	SaO ₂ , percent		COHb Saturation, percent
								Co-Ox	Ear	
Obstructed										
1, F, 69§	COPD	1.66 56	0.86 41	52	7.42	34	71	90	94	6.75¶
2, M, 66	COPD	3.34 56	1.41 44	42	7.41	43	52	84	86	2.0
3, M, 29§	CF	2.04 39	1.21 29	59	7.35	59	60	90	91	1.2
4, F, 49	COPD	1.49 46	0.63 26	42	7.48	45	35	...	73	...
9, M, 60	COPD	0.87 24	0.31 12	35	7.33	52	50	86	88	1.4
10, M, 32	CF	1.20 25	0.76 19	63	7.36	56	53	85	90	2.3
11, M, 61	COPD	1.52 41	0.54 21	35	7.38	61	45	...	84	...
12, M, 61§	COPD	1.14 31	0.53 21	46	7.39	48	58	87	88	1.3
13, M, 59	COPD	1.45 36	0.40 14	27	7.45	52	55	89	89	2.1
14, M, 37§	CF	1.74 31	0.58 13	33	7.34	50	60	88	90	2.1
15, M, 50	COPD	1.66 43	0.70 25	42	7.44	41	48	85	83	1.2
16, M, 59	COPD	1.18 33	0.48 19	41	7.32	56	58	84	86	6.1¶
17, M, 54	COPD	2.55 61	1.45 48	57	7.46	34	54	90	86	1.1
18, M, 57	COPD	2.10 49	0.79 26	38	7.46	28	68	93	91	2.1
19, F, 65	COPD	1.11 44	0.52 29	47	7.43	46	68	94	93	1.8
20, F, 73	COPD	1.91 52	0.55 16	29	7.45	41	66	91	94	4.1¶
Mean	...	1.69 42	0.73 25	43	7.40	47	56	88	88	2.5
SD	...	0.62 11	0.34 11	11	0.05	9	9	3	5	1.8
Restricted										
5, F, 66	IPF	1.26 50	1.18 65	93	7.50	42	36	70	68	1.9
	Thoraco-									
	plasty	0.76 27	0.60 30	79	7.44	52	51	87	88	2.1
6, F, 75	IPF	1.17 26	1.03 33	88	7.42	37	51	84	84	1.5
7, M, 64	IPF	2.05 59	1.57 66	77	7.53	32	57	89	85	5.2¶
8, M, 62	IPF	2.05 59	1.57 66	77	7.53	32	57	89	85	5.2¶
Mean	...	1.31 41	1.10 49	84	7.47	41	49	83	81	2.7
SD	...	0.54 17	0.40 20	8	0.05	9	9	9	9	1.7

*Mean age of obstructed patients was 55 ± 13 years and of restricted patients was 67 ± 6 years.

†CF, Cystic fibrosis; and IPF, diffuse interstitial pulmonary fibrosis.

‡Co-ox, co-oximeter; ear, ear oximeter; COHb, carboxyhemoglobin; and PaCO₂, arterial carbon dioxide tension.

§Studied both at rest and during exercise.

||Studied only during exercise because resting SaO₂ greater than 90 percent (see text).

¶Elevated COHb values for residents of Los Angeles.

regression for the 18 paired samples analyzed by both types of oximeter yielded a correlation coefficient of 0.90 ($p < 0.001$) and a slope of 1.02. This is in agreement with previously reported results;² however, individual differences were as high as 4.5 percent in patients with elevated carboxyhemoglobin values. Due to these variations, all ear oximetric data were adjusted by simple subtraction to reflect the difference between the ear oximetric and spectrophotometric oximetric values obtained simultaneously at baseline.

Figure 2 shows the mean adjusted resting SaO₂ by ear oximeter for air and supplemental oxygen at each flow rate with each type of cannula for subjects with chronic obstructive and restrictive ventilatory disorders separately. Data are presented only for those 17 subjects with resting SaO₂ of 90 percent or less on room air by spectrophotometric oximeter. Table 2 shows the mean values and range in values for the conservation ratios and percentage of savings in oxygen supply in the obstructed and restricted patients separately.

No differences were noted between the saturations achieved when compressed air was delivered through

either the reservoir or standard cannula ($p > 0.3$). In the obstructed patients, mean saturations were significantly higher with the reservoir cannula than the standard cannula when oxygen was delivered at 1 and 2 L/min ($p < 0.0006$). At an oxygen flow rate of 0.5 L/min administered to four subjects via each type of cannula, a similar trend was noted ($p < 0.1$), which, however, did not achieve statistical significance. When data from all 13 obstructed subjects were analyzed, a significantly higher saturation was noted with 0.5 L/min delivered via the reservoir cannula compared to twice this flow rate delivered by the standard cannula ($p < 0.05$). The values for SaO₂ achieved with oxygen flow rates of 1.0, 1.5, and 2.0 L/min delivered by the reservoir cannula are not significantly different from values for SaO₂ attained with 2, 3, and 4 L/min, respectively, delivered via the standard cannula. The mean individual conservation ratio at an SaO₂ of 90 percent is 2.5 ± 0.8 , corresponding to a mean savings in oxygen supply of 60 ± 17 percent, a value significantly different from zero ($p < 0.0001$).

Although the mean values for SaO₂ were higher with

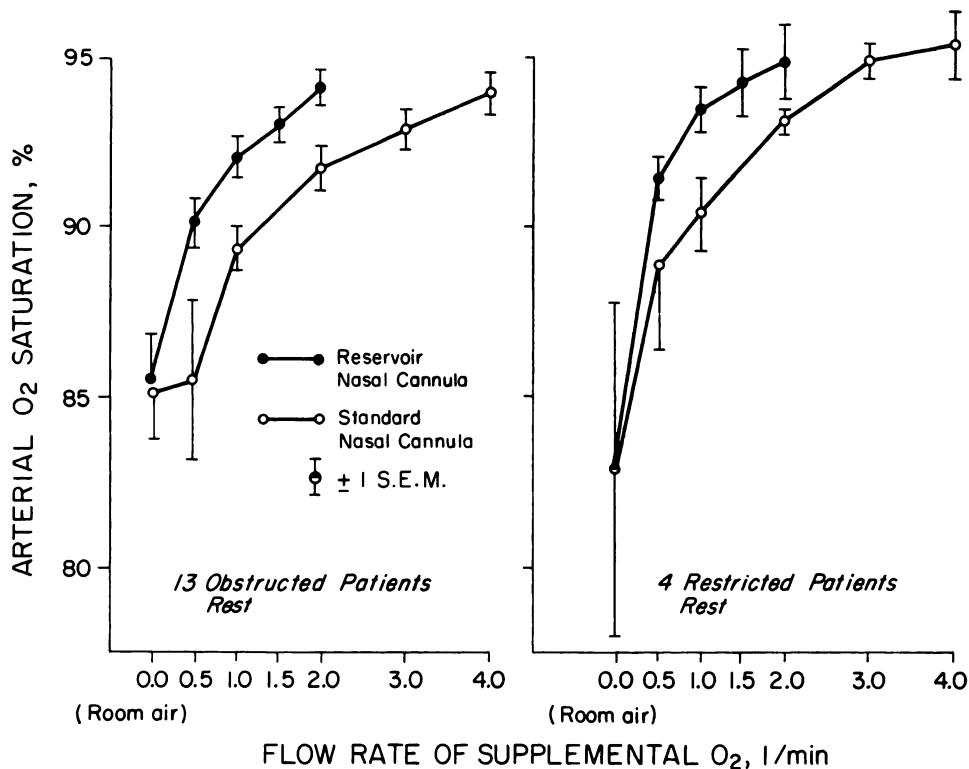


FIGURE 2. Ear oximetric SaO_2 obtained in 13 obstructed and four restricted patients at rest with indicated flow rates of oxygen through reservoir nasal cannula and standard nasal cannula. A flow rate of 0.5 L/min was delivered through the standard cannula in only four obstructed and three restricted patients.

the reservoir than the standard cannula in the four patients with restrictive ventilatory disease when comparable flow rates of oxygen were delivered, these differences were not significantly different by analysis of variance ($p < 0.2$). This is not surprising in view of the small number of such patients studied; however, one of the four restricted patients showed marked oxygen conservation with the reservoir cannula (conservation ratio of 3.5 and oxygen savings of 71 percent).

The oxyhemoglobin saturations observed in the seven patients with obstructive pulmonary disease who exercised breathing room air and oxygen at different flow rates with each type of cannula are shown in Figure 3. The values for SaO_2 achieved with the reservoir cannula at 0.5, 1.0, and 1.5 L/min are comparable to those attained with the standard cannula at twice these oxygen flow rates.

Table 2—Oxygen Conservation Ratios and Percent Savings*

Data	No. of Patients	Conservation Ratio	Percent Oxygen Savings
Obstructed			
Rest	13	2.5 ± 0.8 (1.5-4.0)	$60 \pm 17\uparrow$ (34-75)
Exercise	7	2.9 ± 1.8 (1.1-6.0)	$51 \pm 29\ddagger$ (7-83)
Restricted			
Rest	4	1.6 ± 1.3 (0.8-3.5)	14 ± 40 (-23-71)

*Table values are means \pm SD; numbers within parentheses are ranges.

$\uparrow p < 0.0001$ (Student's *t*-test compared to zero).

$\ddagger p < 0.05$ (Student's *t*-test compared to zero).

ratios at 90 percent during exercise varied from 1.1 to 6.0, with a mean conservation ratio of 2.9 ± 1.8 , corresponding to an oxygen savings of 51 ± 29 percent, which is significantly different from zero ($p < 0.05$).

Most of the patients were observed to inspire nasally at rest. All seven subjects breathed oronasally during

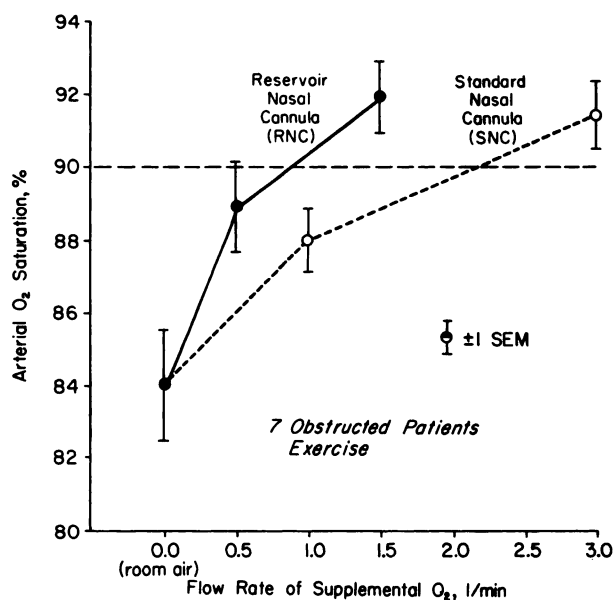


FIGURE 3. Ear oximetric SaO_2 obtained in seven obstructed patients while exercising at 0.75 mph on level grade at indicated oxygen flow rates through reservoir nasal cannula and standard nasal cannula. Dashed line at 90 percent saturation is to aid comparison of oxygen flow rates at that saturation.

exercise. No difference in conservation ratio was noted between the subjects breathing via the nose vs oronasally at rest.

The mean respiratory rate of the obstructed patients at rest while breathing room air was 23 ± 2 breaths per minute and was nearly identical to the respiratory rates observed during oxygen breathing via either cannula at any flow rate. The respiratory rate of the restricted patients during room air breathing was significantly higher (31 ± 3 breaths per minute) than that observed in the obstructed patients ($p < 0.05$). A similar difference in respiratory frequency between the obstructed and restricted patients was also noted during oxygen breathing with either cannula. With exercise the mean respiratory rate of the seven obstructed patients increased significantly ($p < 0.05$) to 28 ± 7 breaths per minute during room-air breathing and did not change significantly while breathing different oxygen concentrations via either cannula. No significant correlation was noted between the conservation ratio or the percentage of oxygen savings and the respiratory rate among all subjects studied either at rest or during exercise ($p > 0.7$).

DISCUSSION

The use of oxygen at 2 L/min continuously by a patient in the Los Angeles area costs about \$400/mo. Over 500,000 persons with advanced COPD are disabled in the United States. If only one in 20 requires ambulatory oxygen, a reduction of oxygen consumption by 50 percent conservatively amounts to \$50,000,000 in annual health-care savings. For the individual patient using 2 L/min continuously, the cost savings even with the additional expense of replacing the reservoir cannula weekly (as recommended by the manufacturers) is \$150/mo if oxygen usage can be reduced to 1 L/min. The reduction of cost at higher oxygen flow rates is even more. For the individual who is able to leave his home with a portable oxygen supply, a 50 percent reduction in flow rate doubles the time one can be away from a stationary supply source of oxygen.

The oxygen-conserving reservoir cannula we have studied is designed to store 20 ml of oxygen flowing from the supply source during the time the patient is exhaling. This reservoir of oxygen is then delivered as a bolus at the beginning of the next breath. This is a very efficient point to deliver the oxygen bolus during the respiratory cycle, since initially inspired gas is distributed to functioning alveoli in most patients. We have shown that this device is capable of producing increases in arterial oxyhemoglobin saturation in hypoxic patients with obstruction equivalent to the increases in saturation produced by the standard nasal cannula at less than half of the oxygen flow rate. With the standard nasal cannula, these patients required 1 to

4 L/min to achieve an SaO_2 of 90 percent at rest. The same results were achieved with the reservoir nasal cannula at flow rates of 0.5 to 2 L/min. The reservoir cannula functioned equally well with the subjects breathing through their nose or through their mouth and nose combined. No conclusion can be drawn about strict mouth breathing, since none of the subjects was a strict mouth breather.

Oxygen saturation in exercising patients frequently decreases below the resting level. Patients requiring low-flow oxygen at rest may need to increase the oxygen flow rate during exercise, and some patients with mild hypoxemia at rest who do not require supplemental oxygen may need oxygen during exercise. The higher flow rates of oxygen via nasal cannula generally required during exercise are due to (1) a lowering of the effective fractional concentration of oxygen in the inspired gas due to the greater dilution of the fixed supplemental flow rate of oxygen by room air during the hyperpnea of exercise, and (2) a tendency for the arterial oxygen tension (PaO_2) in such patients to decrease during exercise due to worsening ventilation-perfusion relationships or diffusion limitation (or both). Because of these differing conditions with exercise, we studied the oxygen-conserving characteristics of the reservoir cannula in seven of our obstructed patients during exercise. In three of these patients, values for SaO_2 were greater than 90 percent at rest. Data for exercise alone are presented for these three patients. As shown in Figure 3, we found that the reservoir cannula resulted in at least as much conservation of oxygen during exercise as we found in the group of 13 obstructed patients studied at rest, despite the greater respiratory frequencies during exercise. These findings indicate that the efficacy of the reservoir cannula is not impaired during the hyperpnea of exercise.

The number of patients with restrictive ventilatory disease in this study did not afford a sufficient sample to draw definite conclusions concerning the utility of the new device for oxygen conservation in this type of patient; however, a marked degree of oxygen conservation (3.5 to 1) was noted in one of the four restricted patients studied. One of the remaining three patients had combined restriction and obstruction. His tidal volume and inspiratory flow rate were so low that the reservoir did not collapse and thus did not deliver a bolus of oxygen. The reservoir acted as a conduit for oxygen, reducing the device to function like the standard cannula in this patient; the oxygen conservation ratio was near one.

The findings in the 13 obstructed patients whom we studied at rest confirm those recently reported by Tjep and colleagues¹ in 20 patients with stable COPD who were evaluated at rest using the same reservoir nasal cannula. Our patients had slightly less obstruction (ratio of the forced expiratory volume in one second

over the forced vital capacity [FEV₁/FVC] of 41.9 ± 11.9 percent; mean \pm SD) than those studied by Tjep et al¹ (FEV₁/FVC of 35.4 ± 4.1 percent), but the level of hypoxemia was slightly greater than in the patients of Tjep et al¹ (85.8 ± 4.5 percent and 88.3 ± 6.8 percent, respectively). We extended the study of oxygen conservation to patients with cystic fibrosis and restrictive disease at rest and obstructed patients during exercise.

Although the reservoir cannula is bulkier and hence less attractive than the standard cannula, this feature did not diminish our patients' interest in this new device for oxygen delivery. Many were anxious to start using the reservoir cannula in an effort to reduce the cost of oxygen therapy and to prolong the duration of time that they could be away from their stationary supply source at home.

Two other oxygen-conserving devices are presently on the market. One (Pendant Oxygen Conserving Cannula; Chad Therapeutics, Inc) is similar in principle to the reservoir cannula tested in this study, except that the reservoir is displaced away from the patient's face.³ This device produces oxygen conservation ratios similar to the device tested in this study. We have had a small number of patients try both devices, and there is no uniformity of preference. The other marketed device is a battery-operated, combination electronic-fluidic device that uses a standard nasal cannula (Demand Oxygen Controller, Cryo-2 Corp). This device regulates oxygen supply so that flow occurs during inspiration and is cut off during expiration. This device decreased usage of supplemental oxygen by 66 percent in 16 patients after surgery.⁴ Comparison of the reservoir cannula and the Demand Oxygen Controller is not possible because the population of patients and the experimental protocols are too dissimilar. Experimental oxygen-conserving devices have been described by Mecikalski and Shigeoka,⁵ by Rinow and Saltzman,⁶ by Crabb et al,⁷ by Anderson et al,⁸ and by others. Additionally, the oxygen-conserving capabilities of percutaneously introduced tracheal catheters, as described by Heimlich,⁹ continue to attract clinical interest.¹⁰

Because of the slightly greater cost and less attractive appearance of the reservoir compared to the standard cannula, it is prudent to document that the reservoir cannula produces significant conservation before prescribing it for any individual patient. If the physician contemplates switching from one type of

oxygen delivery device to another, the patient should be restudied to ascertain the appropriate flow rate of oxygen to be delivered. The patient should also be instructed to adjust the oxygen flow rate appropriately when switching from one type of cannula to another.

In summary, we compared a reservoir nasal cannula for delivering oxygen with a standard nasal cannula in 20 hypoxemic patients with chronic obstructive or restrictive ventilatory disease, at rest or during exercise (or both). Our findings indicate that the reservoir nasal cannula produces improvements in SaO₂ similar to those noted with the standard nasal cannula when half or less of the oxygen flow rate was delivered through the reservoir device compared to the standard cannula. These findings indicate advantages of the reservoir nasal cannula over the standard nasal cannula with respect to the cost of ambulatory low-flow oxygen therapy and extended length of time on portable sources of oxygen. A major challenge will be performance of a prospective study to determine if oxygen-conserving cannulas really produce cost-savings in a long-term clinical setting.

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Conservation of oxygen supply using a reservoir nasal cannula in hypoxemic patients at rest and during exercise

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Improvement of oxygen delivery in severe hypoxaemia by a reservoir cannula

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Improvement of oxygen delivery in severe hypoxaemia by a reservoir cannula.
Ph. Collard, F. Wautelet, J.P. Delwiche, J. Prignot, P. Dubois.

ABSTRACT: In 36 severely hypoxaemic patients (arterial oxygen tension (P_{aO_2}) less than 7.3 kPa or 55 mmHg), candidates for long-term oxygen therapy, we compared the effectiveness of three oxygen-delivery systems, the standard nasal prongs, a so-called oxygen-conserving reservoir device ("Oxymizer Pendant") and the reference pharyngeal catheter, at a preset flow rate of 2 $l \cdot min^{-1}$. After 30 min, the conserving device (OX) was at least as efficient as the pharyngeal catheter (PC) and did significantly better than the nasal prongs (NP), the mean increments in P_{aO_2} and arterial oxygen saturation (S_{aO_2}) being, respectively, 1.1 kPa (8.1 mmHg) and 1.3% higher with OX than with NP. Twenty patients did not reach the target level of 8.6 kPa (65 mmHg) P_{aO_2} with the nasal prongs, but the reservoir cannula allowed nine of these "refractory" patients to hit this therapeutic goal, a result indicating a clear trend towards improved immediate oxygen response. Although initially designed to spare gas, we suggest that a reservoir cannula could serve another purpose, namely to optimize oxygenation in patients treated by an oxygen concentrator. Indeed, since the oxygen flow rate cannot be reliably increased over 3 $l \cdot min^{-1}$ with the available oxygen concentrators, the reservoir device could be more effective in some selected patients whose hypoxaemia cannot be adequately corrected by standard nasal prongs.

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Long-term oxygen therapy (LTOT) is recognized as the mainstay for the treatment of patients with chronic and severe hypoxaemia. There is considerable evidence that home oxygen therapy improves the quality of life and extends survival in proportion to the number of hours of treatment [1-3]. LTOT is recommended for patients in a stable state with an arterial oxygen tension (P_{aO_2}) <7.3 kPa. Patients with a P_{aO_2} of 7.3-8.0 kPa should also be assigned to oxygen supplementation if there is evidence of right heart failure, pulmonary hypertension or erythrocytosis. Oxygen should be administered at a flow rate allowing a P_{aO_2} of at least 8.6 kPa to be reached, in order to increase the arterial oxygen content adequately; furthermore, carbon dioxide retention should not be substantially increased [4].

Since an increasing number of patients are assigned to LTOT, there is considerable interest in improving methods of oxygen administration and conservation, with the perspective of saving costs, increasing the autonomy with portable cylinders and allowing the construction of smaller concentrators [5-8]. Currently available methods include demand-delivery systems that supply oxygen only during inspiration and transtracheal delivery; furthermore, some cannulae are coupled with a reservoir allowing oxygen to be stored during expiration and delivered as a

bolus during the first phase of the next inspiration, when it is most efficient for gas exchange [5, 6].

The purpose of the present study was to compare the efficacy of three oxygen delivery systems, namely the routinely used nasal prongs, the reference pharyngeal catheter and nasal cannulae coupled with a reservoir, in stable patients with severe hypoxaemia meeting the conditions for LTOT. Whether such a device could provide a more efficient oxygenation in patients "refractory" to standard oxygen supplementation was also addressed in this study.

Subjects and methods

Thirty six in-patients (29 men and 7 women; mean age 62.6 yrs) evaluated for LTOT, with severe hypoxaemia at rest (P_{aO_2} <7.3 kPa while breathing room air) and in a clinically stable condition were included in the study; this stable state was confirmed by P_{aO_2} variations of 0.7 kPa or less in 27 of the 32 patients who were re-tested at least 4 weeks apart. Twenty eight had chronic airflow obstruction, 4 had evidence of pulmonary fibrosis and 3 showed a mixed pattern. The forced vital capacity ranged from 22-82% of predicted values, the forced expiratory

volume in one second (FEV_1) from 12–88%, the total lung capacity from 51–145% and the carbon monoxide transfer coefficient from 13–138%. Baseline blood gas values are recorded in table 1.

(SaO_2) of each arterial blood sample was measured with a spectrophotometric oximeter (CO-Oximeter, model 282).

Baseline measurements while breathing room air were compared with those obtained during oxygen supplement-

Table 1. – Arterial blood gas values (36 subjects)

	Room air	Oxygen supplementation 2 l·min ⁻¹		
		Nasal prongs	Pharyngeal catheter	Oxymizer
		NP	PC	OX
SaO_2 %	83 (6)	91 (4)	91 (4)	92 (4)
Pao_2 kPa	5.4 (0.7)	8.9 (2.0)	9.6 (2.5)	10.0 (2.5)
Pao_2 mmHg	49 (5)	67 (15)	72 (19)	75 (19)
$Paco_2$ kPa	6.1 (0.9)	6.4 (1.1)	6.6 (1.1)	6.6 (1.2)
$Paco_2$ mmHg	46 (7)	48 (8)	49 (8)	49 (9)

Data are shown as mean with sd in parentheses.

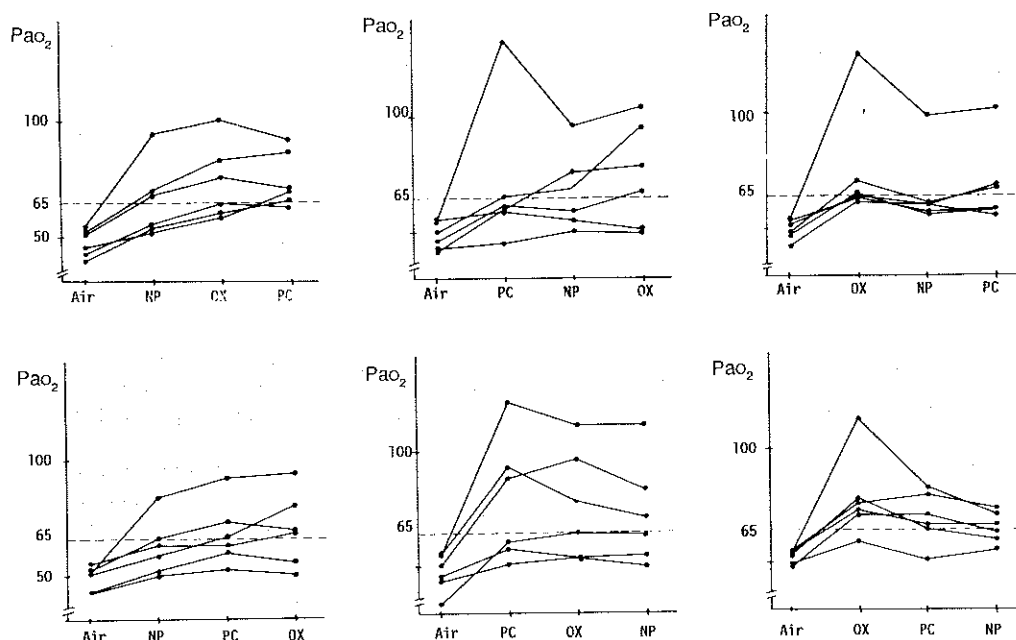


Fig. 1. – Individual evolution of arterial oxygen tension (Pao_2) according to random assignment of the order of use of three modalities of oxygen therapy: nasal prongs (NP), pharyngeal catheter (PC) or Oxymizer (OX).

All subjects gave oral informed consent to participate in the study. Their usual medication schedule was continued, except for inhaled bronchodilators which were withheld for at least 4 h prior to the study.

The patients sat in a comfortable armchair and were allowed to adopt their usual breathing pattern. A catheter was inserted in the radial or brachial artery. Determinations of blood gas levels were performed in a stepwise fashion, using an automated blood gas analyser (Corning Medical, model 175); the oxyhaemoglobin saturation

tation at a flow rate of 2 l·min⁻¹ metered by a calibrated rotameter *via* each considered device: the standard nasal prongs (NP), the pharyngeal catheter (PC) or an oxygen-conserving reservoir system (OX) ("Oxymizer Pendant"; Chad Therapeutics, Woodland Hills, California, USA), the same devices being used throughout the study. The pharyngeal catheter was inserted through the nose to a depth corresponding to the distance measured between the nostril and the ear lobe. The order of use of the devices was assigned randomly. An arterial blood gas

analysis and an oxyhaemoglobin saturation determination were carried out when the patient had been breathing with the first device for 30 min, in order to achieve a steady state; then the patient was switched to the next type of cannula, without discontinuing the oxygen administration and the procedure was repeated so that each patient was tested for all three devices after use of each during 30 min.

In this study, patients "refractory" to oxygen administration are defined as those who do not reach a P_{aO_2} of at least 8.6 kPa when supplemented with $2\text{ l}\cdot\text{min}^{-1}$ oxygen through the nasal prongs for 30 min.

Statistical study was performed by analysis of variance, Student's paired t-test and Chi-squared test; $p < 0.05$ was considered to be significant.

Results

The individual evolution of P_{aO_2} according to random assignment of the order of use of the three modalities of oxygen therapy is shown in figure 1. Average blood gas values are reported in table 1.

At the preset oxygen flow rate ($2\text{ l}\cdot\text{min}^{-1}$), significantly higher average oxygen tension (+1.1 kPa) and oxyhaemoglobin saturation (+1.3%) were achieved after 30 min with the Oxymizer (OX) in comparison with the standard nasal prongs (NP); in all but four patients, OX yielded a higher P_{aO_2} than NP. On average, the P_{aO_2} obtained with OX was higher than that observed with PC, but the difference did not reach the level of statistical significance. A slightly larger increase in carbon dioxide tension was brought about by OX and PC, as compared to NP ($p < 0.05$). The results were not influenced by the order of use of the oxygen delivery systems.

There were interindividual variations in the improvement of P_{aO_2} , 14 of the 36 patients showing only a small increase ($< 0.7\text{ kPa}$), or even a decrease, with OX as compared to NP (fig. 1).

Table 2 reports the respective number of patients reaching three levels of response to $2\text{ l}\cdot\text{min}^{-1}$ oxygen delivered through the three devices. Twenty patients failed to achieve the target level of 8.6 kPa when supplemented through NP; the hypoxaemia of nine of these "refractory" patients was adequately corrected by OX.

Table 2. - Response to oxygen supplementation (n=36)

	NP	PC	OX
$P_{aO_2} > 8.0\text{ kPa}$ or 60 mmHg	23	28	29
$P_{aO_2} > 8.6\text{ kPa}$ or 65 mmHg	16	21	25
$S_{aO_2} > 90\%$	22	27	27

Number of patients reaching three thresholds of response to oxygen therapy with the three considered devices; nasal prongs (NP), pharyngeal catheter (PC), Oxymizer (OX); P_{aO_2} : arterial oxygen tension; S_{aO_2} : arterial oxygen saturation.

Patients "refractory" to oxygen supplementation had a significantly lower baseline P_{aO_2} (6.0 versus 6.7 kPa) and higher arterial bicarbonate (32 versus 29 $\text{mEq}\cdot\text{l}^{-1}$) than the other patients but could not be discriminated on the basis of their spirometric, plethysmographic or carbon monoxide transfer parameters.

Subjective feelings of the patients were somewhat different during the three oxygen supplementation periods. Most patients did not like PC; some considered that the OX cannulae were a little too large and too rigid as compared to NP.

Discussion

An adequate oxygenation is supposed to be achieved in the majority of hypoxaemic subjects with a flow rate of $2\pm 1\text{ l}\cdot\text{min}^{-1}$ oxygen delivered by nasal prongs [4].

It has been extensively shown that oxygen-conserving devices, such as Oxymizer, can achieve the same rise in P_{aO_2} or S_{aO_2} as standard nasal prongs at a lower (about half) oxygen flow rate [5-8].

At first sight, the use of an "oxygen-sparing device" in patients treated by means of oxygen concentrators may not be beneficial since the costs are not directly related to the oxygen flow. The results of our study suggest, nevertheless, that a reservoir cannula could play a role in increasing the response to oxygen supplementation and reducing the number of "refractory" patients; this could be particularly beneficial for an individual patient who does not reach a P_{aO_2} of 8.6 kPa at $3\text{ l}\cdot\text{min}^{-1}$ oxygen with NP.

MOORE-GILLON *et al.* [9] also found a larger increment in transcutaneous oxygen tension with OX than with NP at an oxygen flow rate of $2\text{ l}\cdot\text{min}^{-1}$. The higher S_{aO_2} that we obtained with OX is in perfect accordance with the findings of GOULD and co-workers [10] and MOORE-GILLON *et al.* [9] but lower than the average increment of 3.1% reported by TIEP *et al.* [6] whose patients had, nevertheless, a higher baseline S_{aO_2} .

A clinical problem with LTOT is that a substantial number of patients cannot be adequately oxygenated with a standard $2\text{ l}\cdot\text{min}^{-1}$ flow using nasal prongs: up to 7% of the patients in the Nocturnal Oxygen Therapy Trial (NOTT) study required an NP oxygen flow rate of $4\text{ l}\cdot\text{min}^{-1}$ in order to achieve a suboptimal P_{aO_2} of at least 8 kPa [11]. In our "refractory" patients, the flow rate could indeed have been increased but one should bear in mind that, with standard nasal prong delivery, it may not be possible to substantially increase the oxygen flow because of the irritating effects on the nasal mucosae. On the other hand, oxygen delivered by most of the oxygen concentrators rapidly falls to less than 90% when the flow rate is increased above $3\text{ l}\cdot\text{min}^{-1}$ [12, 13].

The interindividual variations that we observed are also suggested by GOULD and co-workers [10]. The group of "refractory" patients was significantly reduced but not abolished by OX. The presumed mechanisms for the improvement in oxygenation with Oxymizer as compared to standard nasal prongs are the relative independency from the breathing pattern and the bolus effect from the

coupled reservoir during early inspiration; the bolus effect could also be an explanation for the better results obtained with Oxymizer as compared to the pharyngeal catheter even if the difference does not reach the level of statistical significance. With the nasal prongs, the inspired oxygen concentration achieved depends largely on the patient's mouth or nose breathing pattern, a phenomenon in part responsible for interindividual variations in response. GOULD and co-workers [14] have shown that voluntary mouth or nose breathing has no significant effect on the efficiency of the Oxymizer; however, everyone can ascertain that the reservoir does not empty itself during inspiration in case of pure mouth breathing, so that we deem that the Oxymizer behaves exactly like standard nasal prongs when the patient adopts this mode of breathing.

Because of the variation in response and considering the greater cost, it is absolutely necessary to document that the reservoir cannula produces a significant improvement in oxygenation. An individual assessment of each candidate to LTOT is needed and if the patient appears to be "refractory" to standard nasal prong oxygen therapy, a trial with Oxymizer is recommended but the device is prescribed only in case of substantial improvement of oxygen delivery.

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Amélioration de l'oxygénation de patients sévèrement hypoxémiques par des canales nasales à réservoir. Ph. Collard, F. Wautelet, J.P. Delwiche, J. Prignot, P. Dubois.

RÉSUMÉ: Chez 36 patients sévèrement hypoxémiques (P_{aO_2} inférieure à 7.3 kPa ou 55 mmHg), candidats à l'oxygénothérapie au long cours, nous avons comparé l'efficacité de 3 systèmes d'administration d'oxygène, les canules nasales conventionnelles, un système à réservoir dit économiseur ("Oxymizer Pendant") et le cathéter nasopharyngien de référence, au débit préétabli de 2 l·min⁻¹. Après 30 minutes, le système économiseur (OX) était au moins aussi efficace que la cathéter pharyngien (PC) et significativement meilleur que les canules nasales (NP), les gains moyens en P_{aO_2} et S_{aO_2} étant respectivement supérieurs de 1.1 kPa (8.1 mmHg) et 1.3% avec OX par comparaison à NP. Vingt patients n'atteignaient pas le niveau cible de 8.6 kPa (65 mmHg) de P_{aO_2} avec les canules nasales, mais les canules à réservoir permettaient à 9 de ces patients "réfractaires" d'atteindre cet objectif thérapeutique, résultat indiquant une tendance nette à une meilleure réponse immédiate à l'administration d'oxygène. Quoiqu'initialement conçues pour épargner l'oxygène, les canules à réservoir peuvent selon nous être utilisées dans un autre but, celui d'optimiser l'oxygénation chez certains patients traités par un oxyconcentrateur. En effet, comme avec les oxyconcentrateurs actuels le débit d'oxygène ne peut être accru de façon fiable au-delà de 3 l·min⁻¹, le système à réservoir pourrait se révéler plus efficace chez certains patients sélectionnés dont l'hypoxémie ne peut être corrigée adéquatement à des débits faibles par les canules nasales conventionnelles.

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Evaluation of the Pendant Oxygen-Conserving Nasal Cannula during Exercise*

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Evaluation of the Pendant Oxygen-Conserving Nasal Cannula during Exercise*

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There is much recent evidence that patients with chronic pulmonary disease who are hypoxemic benefit from continuous therapy with oxygen. These benefits include reduction in symptoms of cor pulmonale, reduction in mortality, and improvement in quality of life. Oxygen therapy is very expensive, and steady-flow delivery of oxygen is wasteful, since almost the entire benefit of the oxygen presented to the patient occurs at the very beginning of inspiration. We previously described a conserver nasal cannula (CNC) which stores oxygen during exhalation for delivery during subsequent inspirations. The CNC achieves adequate arterial oxygen saturation (SaO_2) at one fourth to one half of the flow in liters of steady-flow oxygen delivery. Because some patients found the mustache configuration objectionable, a pendant nasal cannula (PNC) was designed, displacing the reservoir off of the face and onto the anterior wall of the chest. While both cannulas require some breathing by

nose to function, the PNC is more esthetically acceptable. No studies with exercise have been reported using the PNC. We evaluated the PNC during treadmill exercise in ten subjects with chronic obstructive pulmonary disease and hypoxemia on exercise. We compared the PNC with steady-flow oxygen during steady level treadmill walking sufficient to cause oxygen desaturation while breathing room air at oxygen presentations of 0.5 through 3.0 L/min. At comparable workloads the SaO_2 achieved by PNC required one third of the oxygen flow required by steady-flow oxygen to achieve an equivalent SaO_2 . These differences were statistically significant ($p < 0.01$). We conclude that the PNC provides effective delivery of oxygen during exercise, as well as at rest, while minimizing oxygen flow rate and thus substantially reducing the economic burden normally associated with supplemental oxygen delivery.

Some of the most serious complications of chronic obstructive pulmonary disease (COPD) are caused by hypoxemia.¹ Chronic hypoxemia can cause severe pulmonary vasoconstriction, resulting in elevation in pulmonary arterial pressure and pulmonary vascular

For editorial comment, see page 770

resistance, as well as tissue hypoxia.² When the arterial oxygen saturation (SaO_2) drops below 90 percent, the pulmonary arterial pressure and pulmonary vascular resistance rise rapidly, resulting in cor pulmonale.³ Burrows et al⁴ demonstrated that survival in patients with COPD is inversely related to pulmonary vascular resistance, the clinical outcome of which is "cor pulmonale."^{5,6}

The British study⁷ and the nocturnal oxygen therapy trial study⁸ have demonstrated that patients with COPD who have hypoxemia have improved survival when oxygen was provided during sleep, and further benefit was derived when oxygen therapy was provided continuously. Other studies have demonstrated

that 15 to 18 hours of oxygen therapy daily may be as efficacious as 24 hours, provided the patient resumes adequate oxygen supplementation during sleep and exercise.

Oxygen therapy delivered via a steady-flow nasal cannula is inherently wasteful. This wastefulness results from the fact that steady-flow oxygen is delivered throughout the respiratory cycle, although only early inspiratory delivery contributes substantially to gas exchange.

Because of rising costs of medical care and of oxygen therapy in particular, there has been much recent interest in designing devices and methods of delivering oxygen to reduce the oxygen required to achieve adequate oxygen saturation. Tiep et al⁹ described an oxygen-conserving nasal cannula which stores oxygen during exhalation for delivery during early inhalation. The conserver (Oxymizer, Chad Therapeutics, Inc) was found to reduce the flow of oxygen required to provide adequate saturation during both rest^{9,10} and exercise;¹⁰ however, the conserver was designed such that the reservoir was situated beneath the nose in the region of the mustache, which some patients found esthetically displeasing. Therefore, another conserver cannula was designed, displacing the reservoir off of the face and onto the anterior wall of the chest in a

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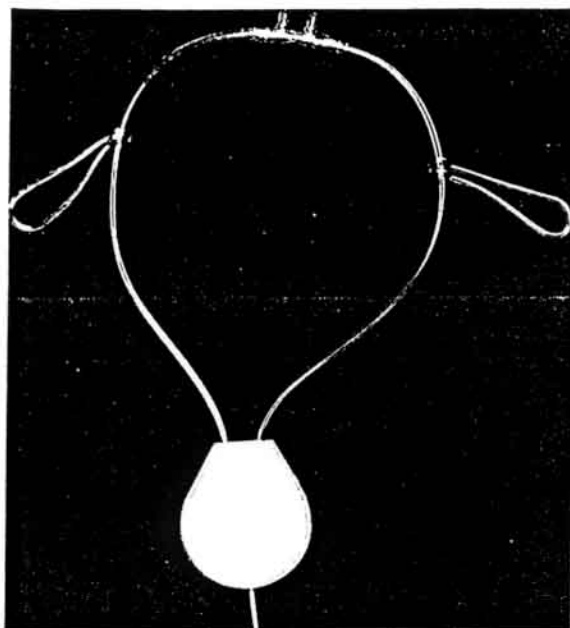


FIGURE 1. Pendant oxygen-conserving nasal cannula.

pendant configuration, where it could be obscured by the patient's clothing.¹¹ The oxygen-conserving advantage of the pendant, as compared to steady flow, was found to be similar to the mustache-shaped device during resting conditions, but no studies during exercise have been reported.

Because of widespread use of these cannulas, particularly in ambulatory patients, we believe that it is important to determine the effectiveness of this cannula during conditions other than rest. In the present study, we evaluated the efficacy of the pendant conserving nasal cannula as compared to steady-flow oxygen delivery during steady-state exercise.

MATERIALS AND METHODS

Pendant Conserving Cannula

The pendant conserving nasal cannula¹¹ (Oxymizer Pendant), as shown in Figure 1, consists of nasal prongs attached to tubular conduit leading to a reservoir bag. The oxygen inlet is located at the junction of the 40-ml reservoir bag and the tubular conduit. While the reservoir bag stores some oxygen, most of the oxygen storage occurs in the 20 ml of tubular conduit. When the patient exhales, sufficient time is allotted for the conducting tubing and reservoir to fill with supplemental oxygen. When the patient is ready to inhale, he will receive a 20-ml bolus of nearly pure oxygen from the conduit, followed by some of the contents of the reservoir.

Protocol

Ten subjects with COPD (seven male and three female subjects) with a mean age of 61 ± 11 years and a mean forced expiratory volume in one second (FEV_1) of 0.70 ± 0.19 L were recruited from the inpatient population of the pulmonary service at the University of Texas Health Center at Tyler. The subjects were mildly hypoxemic at rest, with a recent SAO_2 of 90 percent or less, and they were screened for their tendency to have desaturation during low-level cycle exercise. Exercise testing carried out while breathing room air demonstrated that all subjects had desaturation during low-level exercise, with a mean SAO_2 of 86.3 ± 2.0 percent at a mean power output of 30.5 ± 22.3 W (183 ± 133 kg·m). Informed consent was obtained in accordance with the standards set by the human subjects' investigation committee.

Measurements of pulmonary function were obtained using a rolling-seal spirometer (Cardio Pulmonary Instruments 220). The best of three forced expiratory efforts was recorded for each subject. The carbon monoxide diffusing capacity (D) was obtained using a gas chromatograph (Tensor 7800) according to the method of Jones and Meade.¹² Actual values for D were then compared to predicted values using the data presented by Salorinne.¹³ The data on pulmonary function are shown in Table 1.

All subjects entered into this study were prior participants of a pulmonary rehabilitation program and had demonstrated good exercise tolerance. The exercise consisted of a well-tolerated low steady level walking exercise on a treadmill (Quinton Q-55), with approximately 15 minutes of recovery between each session of exercise. The subjects walked at 1.0 or 1.5 mph for five minutes or until SAO_2 stabilized at each oxygen flow setting. On completion of each stage for testing, for each device, the subject entered immediately into the next higher level of oxygen administration. The performances of the cannulas were compared using identical workloads and time intervals. No patient's SAO_2 was allowed to fall below 80 percent at any time during the study.

The order of choice of presentation of the cannulas was ran-

Table 1—Data from Pulmonary Function Tests

Subject	FVC, L	FEV_1 , L/min	FEV_1/FVC , percent	D, ml/min/mm Hg	D, percent of predicted
Male subjects					
1	1.32	0.72	55	8.24	30
2	2.68	0.88	33	10.84	49
3	1.76	0.76	43	9.45	39
4	1.80	0.64	36	7.21	26
5	2.16	0.88	41	9.56	32
6	1.44	0.60	42	5.31	21
7	3.04	1.04	44	11.25	45
Mean	2.03 ± 0.64	0.79 ± 0.15	42 ± 7	8.84 ± 2.09	35 ± 10
Female subjects					
8	1.52	0.56	37	2.86	13
9	1.68	0.56	33	5.94	26
10	1.28	0.40	31	8.24	31
Mean	1.49 ± 0.20	0.51 ± 0.09	34 ± 3	5.68 ± 2.70	23 ± 9

Table 2—Respiratory Rate, Heart Rate, and SaO₂ in Patients Exercising at Isoexercise Loads and Receiving Various Oxygen Supply Flows

Flow, L/min	Pendant			Standard Nasal Cannula		
	SaO ₂ , percent	Respiratory Rate, breaths per min	Heart Rate, beats per min	SaO ₂ , percent	Respiratory Rate, breaths per min	Heart Rate, beats per min
Room air	93.0 ± 2.4	23.4 ± 15.4	93.8 ± 4.0	93.5 ± 2.3	21.1 ± 6.1	95.0 ± 13.7
0.5	93.4 ± 3.5	20.8 ± 16.1	103.2 ± 4.1	91.2 ± 3.4	22.4 ± 7.0	104.5 ± 15.2
1.0	95.2 ± 2.7	18.8 ± 15.3	101.4 ± 3.3	92.1 ± 3.1	22.9 ± 7.1	105.9 ± 15.8
1.5	96.0 ± 2.3	20.2 ± 16.2	102.1 ± 3.1	93.7 ± 2.8	21.6 ± 8.0	100.1 ± 15.8
2.0	96.7 ± 2.0	18.8 ± 17.2	103.9 ± 2.7	94.4 ± 2.9	24.0 ± 7.4	106.9 ± 13.8
3.0	95.7 ± 2.2	21.2 ± 6.6	104.7 ± 16.0

domized. Oxygen flow was initiated at the lowest level for the first session and then increased to the next level for each successive session. Readings for SaO₂ were taken only after the value stabilized for more than two minutes.

Oxygen saturations were measured using an ear oximeter (Biox IIA), with readings being recorded when the instrument's SaO₂ readings had stabilized. Oxygen supply flow was metered via spirometrically calibrated rotameter (Gilmont, Inc) which could be adjusted within ± 0.05 L/min. We measured SaO₂ with the subject breathing room air and at 0.5, 1.0, 1.5, 2.0, and 3.0 L/min using the standard steady-flow nasal cannula and with room air and at 0.5, 1.0, 1.5, and 2.0 L/min using the pendant conserving nasal cannula. The electrocardiogram was monitored via telemetry (Spacelabs) employing a CM₅ lead placement. Respiratory rate was visually monitored, recording multiple one-minute counts. Data were compared by an analysis-of-variance techniques, followed by Duncan's multiple-range comparison.

RESULTS

The SaO₂, heart rate, and respiratory rate for each level of oxygen administration for all subjects are shown in Table 2. The mean SaO₂ with room air for both cannulas was not significantly different. Oxygen desaturation was improved using supplemental oxygen delivered by either cannula. At 0.5-L/min oxygen supply flow, the pendant achieved a 2.2 percent higher SaO₂ as compared to the steady-flow cannula. At 1.0, 1.5, and 2.0 L/min, the pendant achieved 3.2 percent, 3.3 percent, and 2.3 percent higher than the steady-flow cannula, respectively. These differences were statistically significant ($p < 0.001$). No differences were noted for data on heart rate. Respiratory rates were from 1.6 to 5.7 breaths per minute lower for the pendant when compared to the standard nasal cannula.

A comparison of values for SaO₂ achieved using the pendant and steady-flow cannulas at the various supply flows for each subject at isoworkload is shown in Figure 2. The first point in each panel represents the steady-flow cannula, and the second point represents the pendant conserving at each supply flow. In almost every instance the pendant conserving yields a higher SaO₂ than the steady-flow cannula. In Figure 3, the mean SaO₂ performance curves for the pendant conserving and steady-flow cannula are compared. At 0.5 L/min, the benefit of supplemental oxygen via the pendant

conserving is equivalent to that achieved by the standard nasal cannula at 1.5 L/min. At 1.0 L/min the pendant conserving achieved an SaO₂ equivalent to the steady-flow cannula at 3.0 L/min. Therefore, the savings benefit of the pendant was 3:1 when comparing the pendant conserving to steady-flow oxygen delivery.

DISCUSSION

This study demonstrated that the pendant conserving

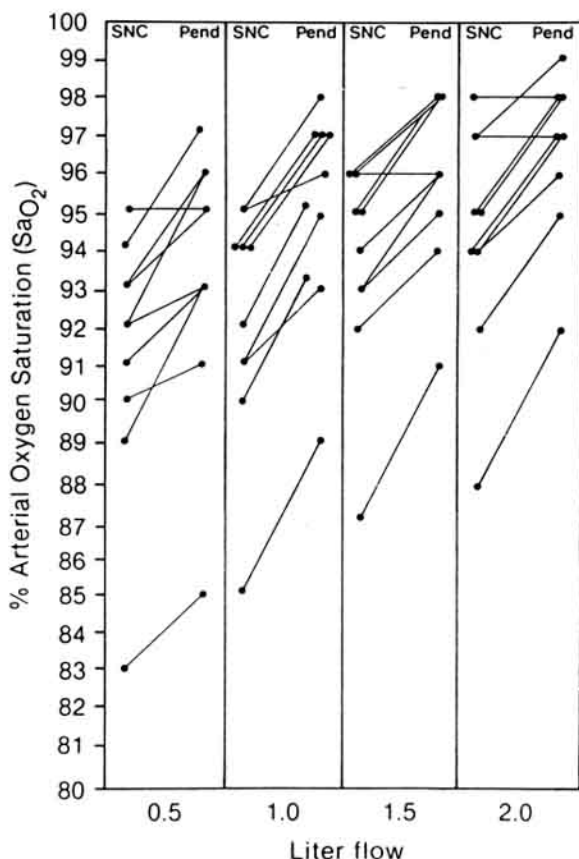


FIGURE 2. Comparison of values for SaO₂ in 20 patients with exercise-induced hypoxemia using standard nasal cannula (squares) and pendant conserving nasal cannula (pluses).

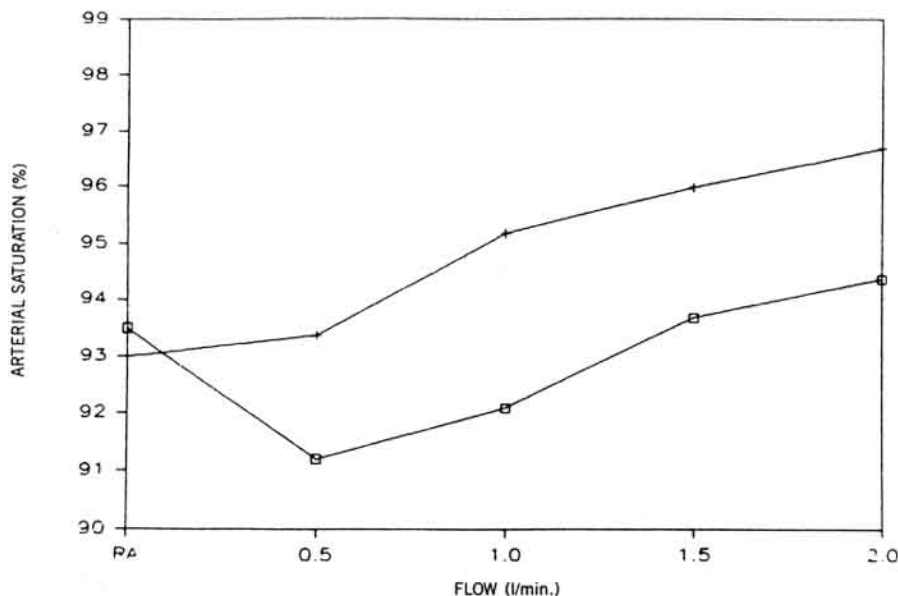


FIGURE 3. Comparison of SaO₂ during exercise for standard nasal cannula (SNC) and pendant cannula (Pend) at 0.5, 1.0, 1.5, and 2.0 L/min of oxygen delivery.

nasal cannula can achieve significantly better SaO₂ than the steady-flow cannula at the same supply flows during exercise. A previous study¹¹ has shown that the pendant conserver nasal cannula is efficacious during resting conditions. In that study the savings benefit of the pendant conserver cannula over the steady-flow cannula was nearly 4:1 at the lowest flows and 2:1 at higher flows. Those findings were consistent with the savings benefit observed in the mustache-shaped conserver nasal cannula during rest.^{9,10,14} In the present study the savings benefit of the pendant conserver cannula over the steady-flow cannula during exercise was 3:1. These findings are consistent with those reported by Soffer et al¹⁰ using the mustache-shaped conserver cannula, in which they also found a savings benefit of 3:1 over steady flow. Thus, the pendant conserver cannula maintains the same savings advantages over steady-flow cannulas as the mustache-shaped conserver cannula, although it is less noticeable on the patient's face.

These oxygen-saving benefits of both conserver cannulas, as compared to steady-flow cannulas, are somewhat predictable. Oxygen delivery by steady flow is inherently wasteful, since only the oxygen delivered during the first portion of inspiration contributes substantially to oxygenation. The conserver cannulas function by storing oxygen during exhalation so that upon early inhalation a bolus of oxygen is added to the steady supply flow. In a previous description of the conserver cannulas,¹⁴ a model was constructed which conceptualized the manner in which the stored oxygen from the reservoir was added to steady supply flow during early inspiration. If 15 to 20 ml of oxygen could be

added to any steady flow, the predicted advantage would be substantial. As the supply flow to the conserver is increased, the margin of advantage would remain substantially the same, but the ratio of savings would tend to diminish.

Because the benefits over steady flow for both rest and exercise are similar, it would be tempting to prescribe oxygen for patients knowing only their oxygen saturation response to the standard cannula at rest. We believe that patients who receive prescriptions for oxygen via either conserver cannula should have their arterial blood gas levels or oxygen saturation tested during both rest and exercise, since individual variation in nasal anatomy and respiratory pattern could affect the delivery of oxygen. Patients who breathe strictly by mouth will probably not derive the added benefit of oxygen conservation, since they must do at least some nasal breathing on both inspiration and expiration to operate the cannula's reservoir membrane. Proper testing will assure adequate oxygen saturation, maximizing effective delivery of oxygen while minimizing the economic burden of oxygen therapy.

Because of the oxygen-saving advantage of the pendant, numerous patients who currently require higher flow rates of oxygen may be able to reduce oxygen flow to lower levels while maintaining their SaO₂ above 90 percent. Perhaps one of the most important aspects of minimizing oxygen flow during ambulation is that it allows the patient to use smaller, more portable oxygen reservoirs or to increase the length of use of existing reservoirs. By using smaller, less cumbersome oxygen reservoirs, patients may then be able

to increase their activities of daily living and assume a more active role in society while at the same time reduce the financial burden of oxygen therapy.

We compared oxygen delivery using the pendant conserver cannula with the steady-flow cannula during treadmill exercise in patients with COPD. Our findings confirm that the pendant conserver cannula is an effective oxygen conserver during exercise as well as rest. These advantages over steady flow could translate into substantial cost savings, improved portability, and extended time away from a stationary oxygen source.

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A M E R I C A N C O L L E G E O F



P H Y S I C I A N S[®]

A New Pendant Oxygen-Conserving Cannula Which Allows Pursed Lips Breathing

Brian L. Tjep, M.D.;* Mary Burns, R.N., B.S.;† and Jackie Herrera, C.R.T.T.†

Multiple benefits of oxygen therapy for hypoxemic patients with chronic lung disease are well established. Steady flow oxygen therapy is inefficient, wasteful and has a high cost. The Oxymizer pendant improves efficiency of oxygen delivery compared with SF. However, the device requires that the patient inhale and exhale nasally to maximize its oxygen-saving properties. When patients do PLB they may not receive full oxygen-saving benefit of the pendant. Yet PLB itself can increase SaO_2 . We evaluated an AP, which does not require nasal exhalation, in nine patients with COPD. We measured SaO_2 while breathing oxygen via SF and the

AP with nasal-only breathing and PLB. Results indicate that the AP maintains an increase in SaO_2 over SF during nasal-only breathing and a further increase during PLB. We conclude that AP acts as an oxygen conserver during PLB; PLB with the AP achieves greater savings than with nasal-only breathing. (*Chest* 1989; 95:857-60)

PLB = pursed lips breathing; SaO_2 = arterial oxygen saturation; AP = auto-resetting pendant; VC = vital capacity; FEV_1 = forced expiratory volume in 1 s; SF = steady flow; FVC = forced vital capacity; CO_2 = carbon dioxide

The benefits of long-term oxygen therapy for hypoxemic COPD patients are well understood and accepted.¹⁻¹⁴ The British Medical Research Council¹³ demonstrated increased survival when oxygen was provided during the night in comparison with no oxygen. The Nocturnal Oxygen Therapy Trial¹⁴ studies demonstrated greater survival when oxygen was provided continuously as compared with 12 h of nocturnal oxygen. Most patients with chronic lung disease, who are prescribed oxygen, are ambulatory and thus require portable oxygen. Patients undergoing pulmonary rehabilitation are taught and encouraged to ambulate as a step toward independence and improving their quality of life.^{15,16} Thus, ambulatory oxygen is an important part of their medical management.

Oxygen therapy is commonly delivered via a SF nasal cannula, which is inefficient and wasteful.¹⁷⁻¹⁹ The waste occurs because SF oxygen is delivered throughout the respiratory cycle, whereas the important delivery takes place during early inspiration. The oxygen delivered during the rest of the respiratory-time cycle is wasted as it is lost to the atmosphere. The amount of oxygen which must be stored represents one of the major limitations of long-term oxygen therapy. For patients receiving portable oxygen, the limitations of oxygen therapy become most evident. Portable oxygen containers must have the oxygen storage capacity to meet the patient's oxygen needs for several hours away from the stationary source.

Because we now perceive a need to reduce the cost

of oxygen therapy and improve upon the portability of ambulatory oxygen, several new devices have been developed to increase the efficiency of oxygen delivery.¹⁷⁻¹⁹ One such device is the Oxymizer pendant, an oxygen-conserving nasal cannula which stores oxygen during exhalation for delivery during early inhalation.²⁰⁻²⁴ The pendant was found to reduce oxygen flow required to provide adequate saturation during both rest²⁰ and exercise conditions.^{21,22} The pendant achieved oxygen savings of between 2:1 and 4:1 as compared to SF delivery.

However, the pendant requires both nasal inhalation and exhalation to maximize its oxygen-saving properties. When patients do PLB they often occlude their nasal passages during exhalation.²⁵ Since PLB is a common breathing retraining technique taught in pulmonary rehabilitation programs, we found it desirable to remodel the pendant so that it will function while the patient is using this method of breathing.²⁵⁻²⁹

In the present study, we evaluated a pendant, which we altered to cause the membrane to spring back to resetting position at the end of inhalation. As a result of this modification, nasal exhalation is not required through the pendant for it to function as an oxygen conserver. We compared the AP in hypoxemic COPD patients, during both PLB and non-PLB with SF oxygen delivery.

METHODS

Pendant Conserver Cannula

The standard pendant conserving nasal cannula²⁰⁻²⁴ (Chad Therapeutics, Inc, Chatsworth, CA; Fig 1) consists of nasal prongs attached to cannula tubing which is connected to the pendant reservoir. Oxygen enters the system at the junction of the tubing and the reservoir. The actual storage of oxygen occurs in the tubing rather

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FIGURE 1. The Oxymizer pendant oxygen-conserving nasal cannula. than in the reservoir. At the beginning of exhalation, the reservoir fills with dead space gas and some oxygen. During most of exhalation, the tubing fills with oxygen. When the patient is ready to inhale, the reservoir provides the means to reflux the oxygen stored in the tubing in addition to the steady supply flow to the patient. The overall effect is early inspiratory delivery of an oxygen bolus.

We modified the pendant so that the membrane of the reservoir does not rely on the patient's exhalation to reset for oxygen storage; it auto-resets. This allows PLB.

Protocol

Nine patients with COPD with a mean age of 69 ± 6.4 years, an FVC of 1.7 ± 0.4 L and an FEV₁ of 0.7 ± 0.2 L were recruited from the inpatient pulmonary rehabilitation program at Casa Colina Hospital for Rehabilitative Medicine in Pomona, CA, and the outpatient pulmonary rehabilitation program at Little Company of Mary Hospital in Torrance, CA. The subjects were hypoxemic at rest and all were on long-term oxygen therapy. Informed consent was obtained in accordance with the standards set by the Institutional Review Boards of the two institutions in which the study was performed.

Pulmonary function measurements were obtained using a calibrated electronic spirometer (Hewlett Packard, Inc, Palo Alto, CA). The best of three forced expiratory efforts was recorded for each subject.

Oxygen saturation values were measured with the use of a Biox IIA ear oximeter (Ohmeda, Inc, Boulder, CO) at rest and at the various flows, allowing sufficient time for equilibration to take place. The order of presentation of the cannulas was randomized but we always started with the lowest supply flows and proceeded to the higher supply flows. Oxygen delivery via SF was set for 1, 2, 3 and 4 L/min, and for the pendant the settings were 0.25, 0.5 and 1.0 L/

min both during non-PLB and PLB. The PLB was taught by a nurse according to a previously set method used in our former study which demonstrated a significant increase in SaO₂ by the technique in patients breathing room air.²⁰ All of the patients in this study were experienced pursed lips breathers. We closely monitored the patients to assure that they were using the appropriate breathing method for each section of the study. Oxygen supply flow was metered via spirometrically calibrated settings of a liquid oxygen system (Liberator Stroller). Data were compared by analysis of variance techniques followed by Duncan's multiple range comparison.

RESULTS

Oxygen saturation performance curves for SF delivery, and the AP during PLB and non-PLB are shown in Figure 2. Oxygen saturation was improved using supplemental oxygen delivered by either cannula. At 0.25 L/min, the AP, during non-PLB and PLB, achieved the equivalent of SF at 1 and 1.7 L/min, respectively. At 0.5 L/min, the AP, during non-PLB and PLB, achieved the equivalent of steady flow at 2.3 and 2.9 L/min, respectively. At 1 L/min, the AP, during non-PLB and PLB, achieved the equivalent of SF at 4 and 4.5 L/min, respectively. In each instance, the AP converter yielded higher saturations than the SF cannula during non-PLB and there was a further increase during PLB. These differences in oxygen requirement to achieve equivalent saturations, between non-PLB and PLB conditions were statistically significant ($p < 0.01$).

The SF equivalents as depicted in Figure 3 demonstrate the oxygen savings using the AP during non-PLB and PLB as compared with SF oxygen. At 0.25 L/min the AP oxygen savings were 4.2:1 and 6.8:1 as compared with SF during non-PLB and PLB, respectively. At 0.5 L/min, the AP oxygen savings were 4.5:1 and 5.8:1 as compared with SF during non-PLB and PLB, respectively. At 1 L/min, the AP oxygen savings were 4:1 and 4.5:1 as compared with SF during non-PLB and PLB, respectively.

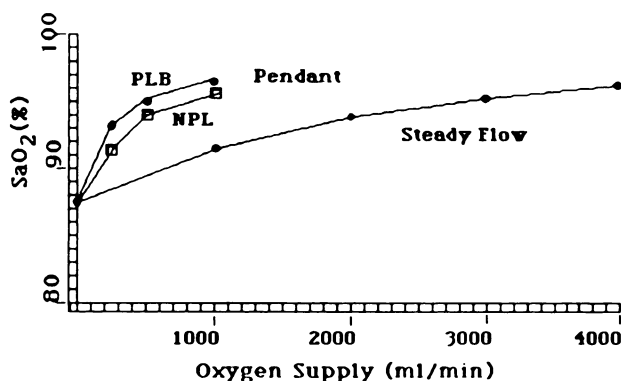


FIGURE 2. Oxygen saturation performance curves for SF delivery, and the AP during non-PLB (NPL) and PLB.

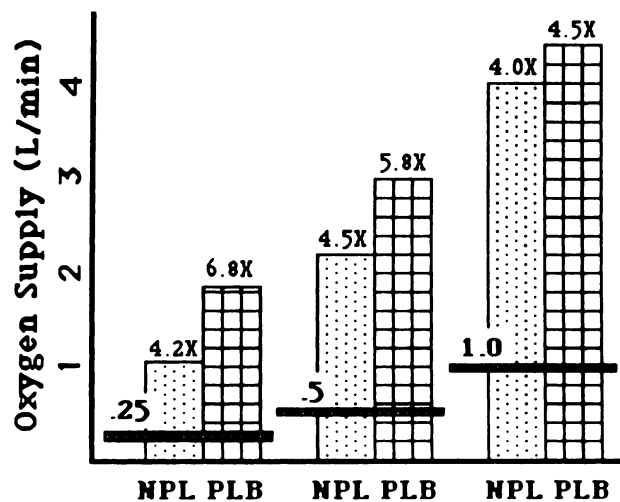


FIGURE 3. Oxygen saturation equivalents during SF as compared with the AP during non-PLB (NPL) and PLB.

DISCUSSION

This study demonstrates that the AP improves the efficiency of oxygen delivery whether the patient is breathing strictly nasally or with pursed lips. The oxygen savings are greater when the patient is doing PLB. This study did not evaluate the standard pendant while the patient does PLB. However, it is known that patients who breathe with pursed lips exhale solely through their mouths²⁵ and the reservoir mechanism of the standard pendant requires nasal exhalation to be able to reset the reservoir membrane. If patients who do PLB completely occlude their nasal passages during exhalation, it is unlikely that they will be able to reset the reservoir membrane in order to benefit from the oxygen-conserving mechanism of the pendant.

Previous PLB studies have demonstrated several benefits of PLB. Patients enjoy the subjective benefit of being able to breathe more comfortably and also the physiologic benefits of increasing the SaO₂ and CO₂ removal.²⁶⁻²⁹ Pursed-lips breathing appears to be a rather natural method that patients discover spontaneously because it relieves dyspnea. Pulmonary rehabilitation programs regularly include PLB retraining as a standard part of their education program.²⁹

Early studies on the pendant demonstrated that the standard pendant oxygen-conserving nasal cannula achieves significantly greater SaO₂ values than the SF cannula during both rest and exercise.²⁰⁻²⁴ In most of these studies the savings benefit of the standard pendant over the SF cannula was 4:1 at 0.5 L/min, 3:1 at 1 L/min and 2:1 at 2 L/min. Those findings were almost identical to those found with the mustache-configured Oxymizer.³⁰⁻³²

The pendant functions by storing oxygen during exhalation for early inspiratory delivery during the next inhalation.²⁰⁻²⁴ The mechanism for oxygen savings

via the pendant is based on the fact that SF oxygen therapy is inefficient and wasteful. If the respiratory-time cycle were divided into thirds, typically two thirds of the time might be spent on exhalation, leaving one third for inhalation.^{19,32} When one examines the inhalation portion of the respiratory-time cycle, the inspiratory flow curve is steepest during early inhalation with relatively more time spent on dead space inhalation. We estimate that one third to one half of inhalation is early inhalation. Thus, one could conclude that about one eighth of the respiratory-time cycle might be spent in early inhalation—contributing to alveolar oxygenation. One might then expect the oxygen saving to approach 8:1 over SF if all oxygen delivery could be effectively focused on early inhalation.

However, the standard pendant does not reach the level of savings suggested by the previously noted model. An explanation is that the patient must exhale through the cannula to reset the membrane and create the chamber. As a result, no oxygen storage is possible during late (dead space) inhalation—wasting some time which could be devoted to oxygen storage. Electronic demand pulsed-oxygen delivery devices such as the Oxymatic do achieve a greater oxygen delivery efficiency because no oxygen is wasted during dead-space inhalation.³³⁻³⁵ The savings reported in the present study are greater than those reported via the standard pendant, particularly at 1 L/min.²⁰⁻²³ We recommend a future study to determine if the AP, which does not wait for exhalation before resetting the membrane, is more or less efficient than the standard pendant.

An earlier PLB study, without supplemental oxygen, demonstrated that patients could be taught to raise their SaO₂ using that breathing retraining technique with the biofeedback guidance of ear oximetry.²⁹ In that study, there was a significant increase in tidal volume, a significant decrease in respiratory rate but no significant change in minute volume. It was the results of that study which inspired the attempt to combine the effects of PLB with the oxygen-conserving properties of the pendant.

The present study did not evaluate PLB on room air vs supplemental oxygen or the standard pendant during PLB. However, we did study PLB at various liter-flows of oxygen using the AP. There was a consistent increase in saturation; hence, the effect was likely to be additive. Also, we found consistently higher saturations via the AP during PLB than achieved by nasal-only breathing for the same liter flow of oxygen. This also supports the notion that the effect of PLB is additive to the oxygen-conserving properties of the pendant.

This study did not evaluate patients under exercise conditions, which would be important in patients using

ambulatory oxygen. Those studies need to be performed prior to widespread clinical use because its most important application is in the ambulatory patient.

In summary, the AP improves oxygen delivery efficiency as compared to SF. In addition, patients can do their PLB and further improve upon their oxygenation. The use of this device could result in substantial cost savings, increased portability and extended time away from the stationary oxygen source.

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Performance of a reservoir nasal cannula (Oxymizer) during sleep in hypoxemic patients with COPD

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A M E R I C A N C O L L E G E O F
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Performance of a Reservoir Nasal Cannula (Oxymizer) During Sleep in Hypoxemic Patients With COPD*

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Study Objective: To determine whether a reservoir nasal cannula (RNC) (Oxymizer) provides an arterial hemoglobin oxygen saturation as measured by pulse oximetry (SpO_2) equivalent to that provided by the standard nasal cannula (SNC) during sleep in hypoxemic patients with COPD while reducing oxygen flow requirement and cost.

Design: The study took place in a sleep laboratory for three nights, with the first night for acclimatization to the new sleeping environment. In a repeated-measures design, on the second and third nights, subjects used the SNC for one night and the RNC on another night. The order in which they received the two devices was counterbalanced.

Subjects: The subjects were patients with COPD who had a stable PaO_2 of 55 mm Hg or less or had a value of 56 to 59 mm Hg with evidence of cor pulmonale or polycythemia (or both) and an FEV₁/FVC of less than 70 percent.

Interventions: A pulse oximeter was used to measure SpO_2 . An arterial blood gas measurement was taken on each night while the patients with COPD were receiving oxygen therapy via the assigned device. An EEG machine was used to record measurements of electro-oculography, chin electromyography (EMG), anterior tibialis EMG and EEG.

Measurements and main results: There was a statistically significant difference between mean SpO_2 during sleep

(RNC, 91 percent; SNC, 93 percent; $F=7.89$; $p=0.01$). Nocturnal SpO_2 was less than 90 percent for 24.2 percent of the time with the RNC and for 17.5 percent of the time with the SNC ($F=5.41$; $p=0.03$), but there was no significant difference in the amount of time that SpO_2 was less than 85 percent. Compared to the SNC, in 4 of 26 patients with COPD, the RNC performed better; in 12 patients with COPD, the RNC performed the same, and in 10 patients with COPD the RNC performed worse during sleep. Sleep parameters were not significantly different between the two devices.

Conclusions: The difference of 2 percent in mean SpO_2 is within the range of SpO_2 measurement error. Therefore, the two devices are equally effective when the sample is considered as a whole. Nighttime oximetry is necessary prior to prescription, since nighttime efficacy of the RNC cannot be predicted on the basis of daytime pulse oximetry.

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RNC = reservoir nasal cannula; SNC = standard nasal cannula; SpO_2 = arterial hemoglobin oxygen saturation measured by pulse oximetry; Ti/T_{tot} = ratio of inspiratory time over total time of respiratory cycle; TST = total sleep time

Two large-scale clinical trials clearly demonstrated the benefits of long-term oxygen therapy for hypoxemic persons with COPD. These studies showed that the use of long-term oxygen therapy prolongs life in this population and that the more hours per day that oxygen is used, the longer life is extended.^{1,2} Since the efficacy of long-term oxygen supplementation is undisputed, the high cost is of interest to the third-party payers who are responsible for funding

medical care, in particular Medicare and the Department of Veterans Affairs (VA). The annual expenditure for home oxygen by Medicare is over \$2 billion, and the yearly expenditure by the VA is approximately \$12 million³ (G. Griggs, written communication, May 23, 1991).

The Oxymizer (Chad Therapeutics, Inc) is a reservoir nasal cannula (RNC) which is worn in a moustache distribution. This RNC stores oxygen during exhalation and then allows for the inspiration of a 20-ml bolus of oxygen during early inhalation.³ This RNC (Oxymizer) was the first oxygen-conserving device to be available commercially, and it has been marketed for its ability to reduce oxygen flow requirement and cost.⁴

Long-term studies proving the efficacy and cost effectiveness of this RNC under field conditions are lacking.⁵ Theoretic calculations concerning the economic advantages for using this RNC have not been convincing,⁶ and a relative lack of research and clinical experience discourages many physicians from prescribing it.

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In addition, there are no published reports describing the performance of the RNC during sleep. It is quite possible that oxygen flow requirements via the RNC may be different during sleep, since sleep is a different state than wakefulness. This study sought to determine whether the RNC provides an arterial hemoglobin oxygen saturation as measured by pulse oximetry (SpO₂) equivalent to that provided by the standard nasal cannula (SNC) during sleep in hypoxemic patients with COPD while reducing oxygen flow requirement and cost.

MATERIALS AND METHODS

Our prescreening process consisted of obtaining information concerning age, race, marital status, activity level, occupational status, smoking behavior, and current used home oxygen delivery system. Height and weight were measured. Pulmonary function tests were performed, which included room-air PaO₂, percent oxyhemoglobin, percent carboxyhemoglobin, percent methemoglobin, PaCO₂, pH, HCO₃⁻, FEV₁ (percent of predicted); forced vital capacity (FVC, percent of predicted); FEV₁/FVC, diffusing capacity for carbon monoxide (D, percent of predicted), total lung capacity (TLC), residual volume (RV), and functional residual capacity (FRC). Seated and supine measurements of respiratory rate and the ratio of inspiratory time over the total time of the respiratory cycle (Ti/Ttot) were recorded while the patients with COPD were using the RNC and while they were using the SNC. Reasons for exclusion of patients included a resting room-air PaO₂ greater than 59 mm Hg, patient's refusal, or infectious exacerbation of COPD.

The oxygen flow rate (in liters per minute) by SNC used at night was determined on the basis of daytime resting, seated oximetric testing. The oxygen flow rate by SNC that achieved an SpO₂ of 91 percent or more (≥88 percent for hypercapnic patients) was chosen for the study. Although it is common practice to increase a patient's oxygen dose by 1 L/min during sleep,^{1,7} it is not a universal practice.⁸ In this study, we sought to determine empirically the oxygen flow required to maintain adequate oxygenation (SpO₂, 91 to 95 percent) as recommended by the American Thoracic Society.⁷

The oxygen flow rate by RNC used at night was also determined on the basis of daytime resting seated oximetric testing. The oxygen flow by RNC that achieved an SpO₂ equivalent to that achieved by 2 L/min via SNC was chosen for the study; however, since it is known that many patients with ventilation/perfusion (\dot{V}_A/\dot{Q}) abnormalities increase the \dot{V}_A/\dot{Q} mismatch and decrease lung volume in the supine position, supine SpO₂ measurements were also examined on the same day while the patients with COPD were using the SNC and again while they were using the RNC.

We studied 26 male hypoxemic patients with COPD (PaO₂ ≤ 55 mm Hg or PaO₂ of 56 to 59 mm Hg with cor pulmonale or polycythemia [or both], FEV₁/FVC < 70 percent, no unstable medical or psychiatric illness, and no infectious exacerbation of COPD in the preceding 4 weeks). The study took place in the sleep laboratory for three nights, with the first night for acclimatization to the new sleeping environment. A repeated-measures design was used, and each patient with COPD used the SNC for one entire night and the RNC on another night. The order in which they received the two devices was counterbalanced, with each patient serving as his own control. Hence, half of the patients with COPD received the SNC followed by the RNC and half received the RNC followed by the SNC. Data from the first night were not analyzed.

A pulse oximeter (Ohmeda Biox model 3760) was used to measure SpO₂ throughout the night. This specific oximeter is designed to calculate the following summary statistics from continuous SpO₂ recordings: lowest SpO₂; mean SpO₂; percentage of time SpO₂ is less than 90 percent; percentage of time SpO₂ is less than 85

percent; percentage of time SpO₂ is less than 80 percent; and percentage of time SpO₂ is less than 70 percent. A repeated-measures analysis of variance (ANOVA) was used to compare differences between devices and between days for these outcome variables. In addition, an arterial blood gas measurement was taken on each night just before the sleep study was started while the patient was receiving oxygen therapy via the assigned device. The arterial blood gas analysis was done in order to assure that the clinical condition of each participant in the study was comparable between the second night and the third night of the study. Patients with COPD were excluded from participation if their PaCO₂ differed by 10 mm Hg or more.

An EEG machine (Nihon Kohden model 4217) was used to record measurements of electro-oculography (EOG), chin electromyography (EMG), anterior tibialis EMG, and EEG. Respiration was monitored by detecting respiratory movements at the abdomen and chest with a strain gauge and by detecting airflow at the nose and mouth with a thermistor. The EEG paper was used for polysomnography at a paper speed of 15 mm/s in order to allow for the visual scoring of sleep stages and episodes of apnea/oxygen desaturation. We did not specifically monitor the sleepers for "mouth-open" and "mouth-closed" conditions. Total sleep time (TST), sleep stages 1 to 4, rapid-eye-movement (REM) sleep, arousals, awakenings, apneas, and sleep efficiency (the ratio of TST divided by time in bed) were determined from analysis of the continuous recordings. A repeated-measures analysis of variance (ANOVA) was used to compare differences between devices and between days for these outcome variables. In addition, we compared the sleep variables obtained in our patients with COPD to the sleep variables of the

Table 1—Daytime Resting Seated Versus Supine SpO₂ Comparison

Patient	RNC			SNC		
	Flow Rate, L/min	Mean SpO ₂ , %		Flow Rate, L/min	Mean SpO ₂ , %	
		Seated at Rest	Supine		Seated at Rest	Supine
1	1	91	91	2	91	92
2	1	94	94	2	95	95
3	0.5	96	94	2	97	97
4	1	95	96	2	95	97
5	1	93	90	2	93	86
6	1	91	91	2	91	92
7	0.5	92	84	2	92	89
8	1	88	89	2	90	91
9	1	93	94	2	94	94
10	1	97	96	2	97	98
11	1	92	89	2	92	90
12	0.5	92	94	2	93	94
13	1	95	95	2	96	94
14	0.75	93	93	2	93	93
15	1	92	...	2	93	...
16	0.75	92	94	2	92	95
17	1	91	92	2	92	91
18	0.5	92	92	2	91	92
19	0.75	95	94	2	95	95
20	1	90	94	2	93	92
21	1	91	92	2	93	95
22	0.75	89	89	2	91	93
23	1	91	92	2	92	93
24	1	91	92	2	91	92
25	1	93	95	2	94	93
26	0.5	91	91	2	92	92

*Unable to lie supine.

normal aged population as found in the literature.⁶

Mean demographic data (\pm SD) pertaining to the participants in the study are listed in the following tabulation:

Mean age, yr	65 \pm 7
Mean height, cm	177 \pm 7
Mean weight, kg	87 \pm 21
Mean room-air PaO ₂ , mm Hg	55 \pm 4
Mean FEV ₁ , % of predicted	34 \pm 17
Mean FVC, % of predicted	57 \pm 21
Mean FEV ₁ /FVC, %	44 \pm 12
Mean D, % of predicted	47 \pm 26
Mean TLC, L	6.18 \pm 1.7
Mean RV, L	3.58 \pm 1.4
Mean FRC, L	4.36 \pm 1.5
Mean Ti/Ttot (sitting at rest)	0.4 \pm 0.2
Mean Ti/Ttot (supine)	0.4 \pm 0.2
Mean respiratory rate (sitting at rest)	19 \pm 6
Mean respiratory rate (supine)	19 \pm 6
Current oxygen usage, h/day	16.5 \pm 8.0

Four of the 26 patients with COPD had evidence of restrictive lung disease (TLC < 80 percent of predicted), 18 out of 26 had evidence of cor pulmonale, and 16 out of 26 had evidence of reversible airways disease. Upright and supine measurements of SpO₂ are shown in Table 1. Demographic data were analyzed for differences between participants in the study and eligible subjects who declined to participate using χ^2 analysis and *t* tests for independent samples.

Three of the patients with COPD were using a liquid oxygen system at home, four were using an oxygen concentrator machine, six were using H and E tanks, ten were using a concentrator and E tanks, and three refused to use home oxygen therapy. We calculated our VA hospital's cost savings comparing use of the SNC with use of the RNC in each of the patients with COPD for whom the RNC was efficacious at night, using their actual equipment costs.

RESULTS

We found no significant differences between the 26 included hypoxemic patients with COPD and the 47 excluded patients, except for the measurement of room-air PaO₂ before the study. The difference in room-air PaO₂ before the study (included patients, 55 mm Hg; excluded patients, 60 mm Hg) was due to the fact that only patients with COPD who had a resting room-air PaO₂ of 59 mm Hg or less were included in the study. Therefore, there was no systematic bias in sample inclusion.

We found no difference between the arterial blood gas values on the second night and the third night, except for pH. The difference in pH, although statistically significant (*p* = 0.01), is only a difference of 0.02 (7.41 – 7.39), and it does not have clinical significance. Therefore, the clinical condition of the patients with COPD on the second night was equivalent to that on the third night.

During sleep, there was a statistically significant difference (*F* = 7.89; *p* = 0.01) between the mean SpO₂ of 91 percent and 93 percent for the RNC and SNC, respectively (Fig 1). In 23 out of the 26 subjects (88 percent), mean SpO₂ during the use of the SNC was the same or higher than it was during use of the RNC (Fig 2). In addition, nocturnal SpO₂ was less than 90 percent for 24.2 percent and 17.5 percent of the time for the RNC and SNC, respectively (*F* = 5.41; *p* = 0.03). There was no significant difference between

the devices in the amount of time the SpO₂ was less than 85 percent during sleep (Fig 3).

Data on each individual subject revealed that 13 out of 26 hypoxemic patients with COPD (50 percent) were adequately oxygenated (mean SpO₂ \geq 92 percent; SpO₂ \geq 90 percent for 93 percent of the time) during sleep while using 2 L/min via SNC, and 12 out of 26 hypoxemic patients with COPD (46 percent) were adequately oxygenated during sleep while using the RNC. Eleven out of 26 hypoxemic patients with COPD (42 percent) were suboptimally oxygenated during sleep, both while using the SNC and the RNC, as judged by these rather strict criteria, while using flow rates based upon daytime pulse oximetric testing (Table 2). The RNC performed better than the SNC in 4 patients (15 percent), and the RNC performed the same as the SNC in 12 patients (46 percent); however, the RNC performed worse than the SNC in 10 patients (39 percent); and for 4 of these subjects, the RNC performed much worse than the SNC (Table 2). Multivariate analyses did not reveal any reliable predictors of nighttime efficacy for the RNC.

The TST, percent REM sleep, percentage of time in sleep stages 1 to 4, arousals, awakenings, apneas, and sleep efficiency were not significantly different between the two devices (Table 3). The night sleep of our patients was disrupted and light, as compared to normal subjects.⁸ Normally, the sleep of older adults

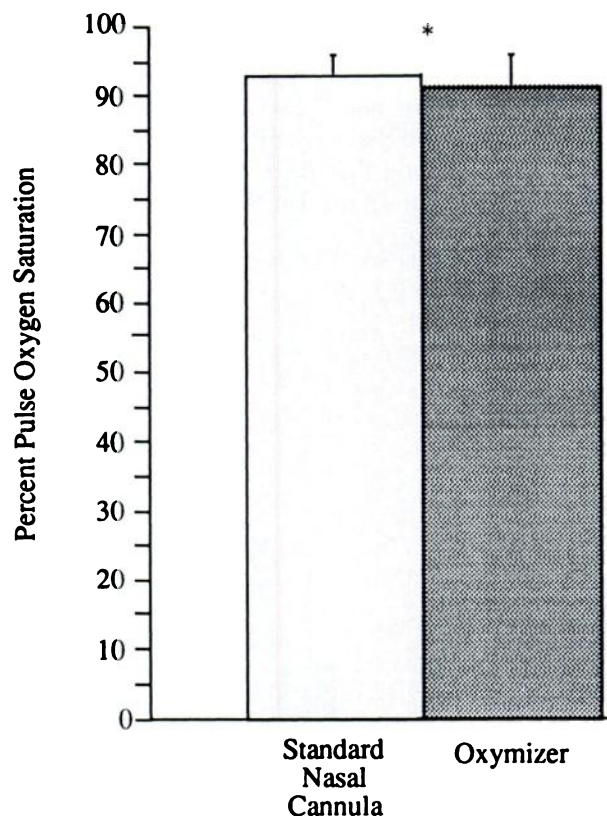


FIGURE 1. Mean (\pm SD) SpO₂ for two nights with oxygen supplied by SNC and RNC. Asterisk indicates *p* < 0.01 for SNC versus RNC.

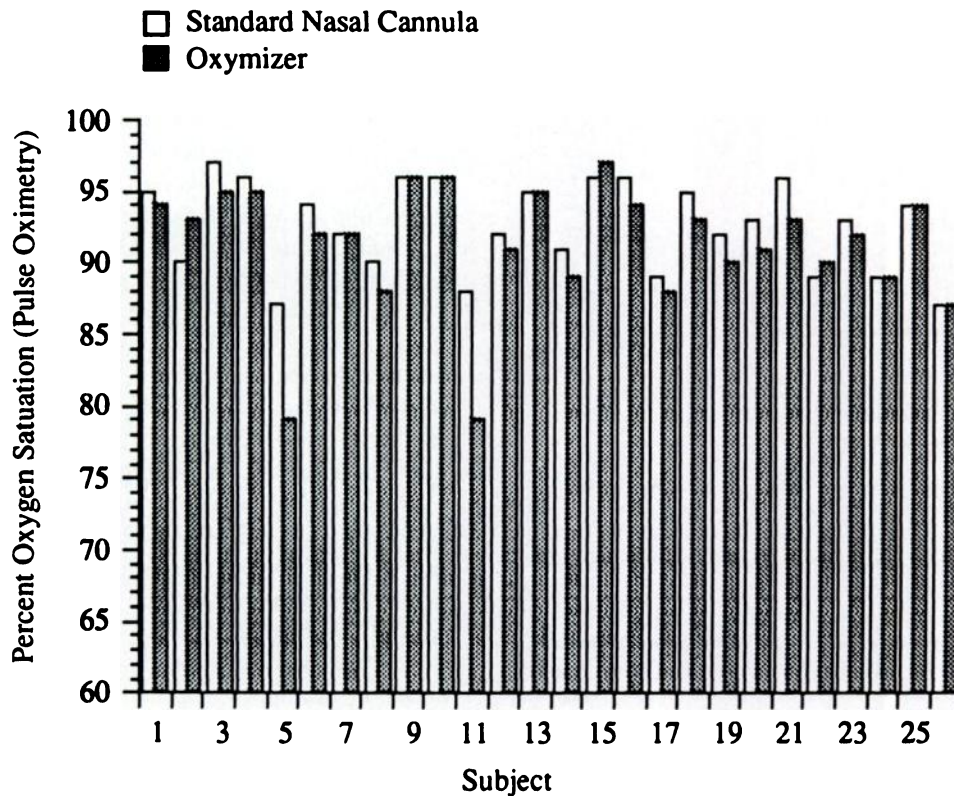


FIGURE 2. Mean SpO₂ for each subject with oxygen supplied by SNC or RNC.

is less efficient and lighter than that of the young, with greater amounts of light non-REM sleep (stages 1 and 2) and more arousals and awakenings.⁸ In comparison with this, our patients, as a group showed an even greater increase in non-REM stage 1 and in stage shifts per hour, and they demonstrated a poorer sleep efficiency. We found that their REM sleep was disturbed as compared to that of the normal aged

population. In addition, their total REM sleep was decreased, and they had fewer REM periods.

The average flow used with the RNC was only 44 percent of that used with the SNC (Table 1). Usage of the RNC by the 16 subjects for whom it proved to be efficacious at night resulted in a 56 percent O₂ savings (Table 2), and we inferred VA cost savings from this. (See appendix for a description of the model used to calculate VA cost savings.)

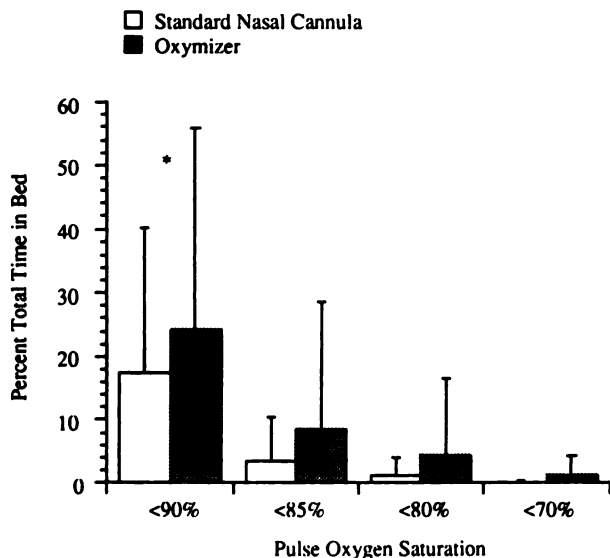


FIGURE 3. Mean (+SD) percentage of total time in bed below SpO₂ of 90, 85, 80, and 70 percent with oxygen supplied by SNC and RNC. Asterisk indicates $p < 0.03$ for SNC versus RNC.

DISCUSSION

We conclude that the two devices are equally effective. The observed magnitude of difference in mean SpO₂ between the RNC and SNC (2 percent), while statistically significant, may be of little clinical relevance. Additionally, the mean difference in SpO₂ between devices fell within the range of measurement error for pulse oximetry. The mean percentage of total time in bed during which subjects' SpO₂ was less than 90 percent, 85 percent, 80 percent and 70 percent was consistently higher under the RNC condition, as compared to SNC; however, only the difference in the SpO₂ range less than 90 percent and greater than 85 percent was statistically significant.

This study demonstrated that nighttime efficacy of the RNC cannot be predicted on the basis of daytime oximetric testing. This is indicated by the fact that the RNC device was not efficacious in 10 out of 26 hypoxemic patients with COPD (39 percent) during

Table 2—Nighttime SpO₂ Readings

Patient	RNC Flow Rate, L/min	Mean SpO ₂ , %		Percent of Time								RNC Category*
				SpO ₂ <90%		SpO ₂ <85%		SpO ₂ <80%		SpO ₂ <70%		
				SNC	RNC	SNC	RNC	SNC	RNC	SNC	RNC	
1	1	95	94	0	0	0	0	0	0	0	0	1
2	1	90	93	27	1	0	0	0	0	0	0	2
3	0.5	97	95	0	0	0	0	0	0	0	0	1
4	1	96	95	0	1	0	0	0	0	0	0	1
5	1	87	79	63	97	20	75	7	48	0	11	3
6	1	94	92	5	19	0	0	0	0	0	0	3
7	0.5	92	92	8	5	0	0	0	0	0	0	1
8	1	90	88	31	47	1	18	0	3	0	1	3
9	1	96	96	0	0	0	0	0	0	0	0	1
10	1	96	96	0	0	0	0	0	0	0	0	1
11	1	88	79	58	99	19	73	7	45	1	12	3
12	0.5	92	91	9	15	0	2	0	0	0	0	3
13	1	95	95	0	0	0	0	0	0	0	0	1
14	0.75	91	89	20	55	1	3	0	0	0	0	3
15	1	96	97	0	0	0	0	0	0	0	0	1
16	0.75	96	94	0	0	0	0	0	0	0	0	1
17	1	89	88	54	62	7	17	0	3	0	0	3
18	0.5	95	93	0	1	0	0	0	0	0	0	1
19	0.75	92	90	8	36	0	1	0	0	0	0	3
20	1	93	91	15	16	7	0	1	0	0	0	2
21	1	96	93	0	5	0	0	0	0	0	0	3
22	0.75	89	90	47	37	5	5	0	0	0	0	2
23	1	93	92	0	3	0	0	0	0	0	0	1
24	1	89	89	52	59	9	1	2	0	0	0	2
25	1	94	94	2	0	0	0	0	0	0	0	1
26	0.5	87	87	55	71	23	24	11	7	1	2	3

*Category 1, RNC performed *same* as SNC during sleep (mean SpO₂ within 2%; % of time SpO₂ <85%, <80%, or <70% the same; and less than 7% difference in % of time SpO₂ <90%); category 2, RNC performed *better than* SNC during sleep (mean SpO₂ achieved with RNC 2% or higher than mean SpO₂ achieved with SNC; and % of time SpO₂ <90%, <85%, <80%, or <70% greater with SNC); and category 3, RNC performed *worse than* SNC during sleep (mean SpO₂ achieved with RNC 2% or lower than mean SpO₂ achieved with SNC; % of time SpO₂ <90%, <85%, <80%, or <70% greater with RNC; and mean SpO₂ <88% with RNC).

sleep, even though it appeared to be efficacious during daytime rest. We conclude that oximetric testing is necessary during sleep, as well as during daytime rest and exercise, if nighttime use of the RNC is contemplated.

The exact mechanism causing the RNC to fail to maintain acceptable arterial hemoglobin oxygen saturation with reduced flow rates when used by some hypoxemic patients with COPD is not known. Some investigators have hypothesized that mouth breathing

or a rapid respiratory rate or both are factors in reducing the efficacy of the RNC.^{9,10} Further research is necessary concerning the use of this device with hypoxemic patients with COPD. The performance of the RNC should be examined closely during the conduct of activities of daily living and during the presence of respiratory tract infection. In addition, the performance variability of the RNC should be compared to the performance variability of the SNC when used by hypoxemic patients with COPD in the

Table 3—Mean Values (±SD) Obtained During Nighttime Sleep Studies

Data	SNC	RNC	F	p Value
Oxygen flow rate, L/min	2.0±0	0.87±0.2
Sleep				
TST, min	206.2±57.7	212.5±58.3	0.42	0.52
% REM	16.4±8.4	16.3±8.5	0	0.95
% Stages 1 and 2	80.2±11.5	80.9±11.0	0.06	0.81
% Stages 3 and 4	3.1±8.1	2.6±5.7	0.08	0.78
Arousals	46.7±43.7	51.0±48.0	0.28	0.60
Awakenings	14.9±10.1	13.9±9.0	0.49	0.49
Apneas, non-REM	13.7±39.7	10.4±25.6	1.09	0.31
Apneas, REM	1.7±4.7	2.0±5.1	0.21	0.65
Sleep efficiency	63.6±18.0	65.3±19.0	0.93	0.34

stable chronic state.

This study tends to confirm the common practice of increasing oxygen flow rate by 1 L/min during sleep, since 50 percent of our participants were suboptimally oxygenated during sleep while using their daytime oxygen flow rate; however, when reimbursement is directly linked to oxygen flow rate reduction (for example, when H tanks or liquid oxygen is used), it is cost-effective to perform nighttime oximetry in order to verify that this increase in flow rate and cost is necessary, since 50 percent of our participants were adequately oxygenated during sleep while using their daytime oxygen flow rate.

The cost to the VA for home oxygen equipment is based upon oxygen flow whenever a liquid or a gas delivery system is prescribed, and each reduction in oxygen flow results in a reduction in cost. Use of the RNC by VA patients would result in a significant savings, and the cost for day and nighttime oximetric testing would not overshadow this savings. On the other hand, Medicare reimburses for home oxygen at a fixed rate for patients using a flow of 1 to 4 L/min. The Medicare system is already saving as a result of its instituting this fixed-rate reimbursement system, but the home medical equipment suppliers' costs have risen. Use of the RNC by Medicare patients would enable home medical equipment suppliers to continue to provide portable oxygen while holding their costs down, as a result of reducing the number of required home deliveries per month.

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APPENDIX

We calculated the cost savings of our VA hospital comparing use of the SNC with use of the RNC in the 16 patients with COPD for whom the RNC proved to

be efficacious for use during sleep. Use of the RNC by these patients at their required oxygen flow rates, using the actual cost for their specific equipment, generates an overall savings of \$705.29 per patient per year based upon 1991 costs to our hospital. This cost-savings figure is based upon 24-h usage; it operates under the assumption that the RNC would be efficacious during exercise, and it incorporates the cost for the RNC with weekly replacement. It does not include the cost for nighttime oximetric testing.

We conclude that based upon estimates of approximately 8,500 VA patients receiving long-term oxygen therapy (G. Griggs, written communication, May 23, 1991) 80 percent of whom use 2 L/min or more and could thus be considered for use of the RNC and 61 percent for whom the RNC would be efficacious, with yearly per-patient cost savings of \$705.29, the VA could save about \$3 million per year or approximately 25 percent of total costs by using the RNC.

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