

A Comparison of the OxyArm Oxygen Delivery Device and Standard Nasal Cannulae in Chronic Obstructive Pulmonary Disease Patients

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OBJECTIVE: Compare the performance of the OxyArm to that of nasal cannulae in the delivery of supplemental oxygen to patients with chronic obstructive pulmonary disease. **METHODS:** We tested various oxygen flows with 10 chronic obstructive pulmonary disease patients who were receiving prescribed supplemental oxygen. Blood oxygen saturation (measured via pulse oximetry [S_{pO_2}]), was measured with each device, and mean data were compared with paired, 2-sample *t* tests. **RESULTS:** Mean S_{pO_2} was equivalent with OxyArm and nasal cannulae for 7 of the 10 subjects, over a range of oxygen flows (2–5 L/min). Mean S_{pO_2} was higher with the OxyArm with 2 subjects and lower with 1 subject ($p < 0.01$). **CONCLUSION:** The OxyArm maintained stable S_{pO_2} over the range of oxygen flows studied and at levels equivalent to those maintained by nasal cannulae in 9 of the 10 subjects. The OxyArm does not contact the face and may be ideal for patients on long-term home oxygen therapy. *Key words:* OxyArm, oxygen, mask, nasal cannulae, chronic obstructive pulmonary disease, COPD, long-term oxygen therapy, LTOT, hypoxia. [Respir Care 2003;48(2):120–123]

Introduction

Treatment of respiratory insufficiency most often necessitates long-term,¹ perioperative, and postoperative² supplemental oxygen. Furthermore, long-term oxygen therapy improves survival in patients with chronic obstructive pulmonary disease and chronic hypoxemia.^{3,4} Oxygen is most often administered using face mask or nasal cannulae (NC). The various available masks and NC differ in terms of the fraction of inspired oxygen delivered, which is generally a function of oxygen flow and the patient's compliance with specified use.^{5–7} The standard oxygen mask ensures oxygen enrichment of inspired air for nose and mouth

breathing. However, some patients describe these devices as uncomfortable, and increased dead space can be important with patients with borderline hypoventilation.⁸ Postoperative nausea and vomiting, restlessness, routine mouth care, and eating all lead to mask displacement, resulting in no oxygen delivery at all.⁹ NC are generally well tolerated and reliable. However, there are situations (eg, nosebleed or deviated septum) in which it is desirable to deliver oxygen in a manner that avoids contact with the nasal mucosa or in which NC are not well tolerated. NC lie in close proximity to mucous membranes. With dry air flow NC can cause local irritation, infection, and bleeding.^{8,10} Subcutaneous emphysema is a rare complication.¹¹ Mouth breathing while talking or snoring, though not a contraindication to NC oxygen therapy, is a potentially underestimated problem with NC,¹² since oxygen delivery efficiency can be reduced.^{13,14}

Both the traditional mask and nasal cannulae devices are widely used and have attractive safety profiles. However, though incremental design improvements have been made, these have largely gone unsubstantiated in the literature. The OxyArm (Southmedic, Barrie, Ontario, Canada) was designed to address some of the documented and anecdotal issues associated with face masks and NC, while maintaining functional equivalence. We previously described the development of this minimal-contact, open de-

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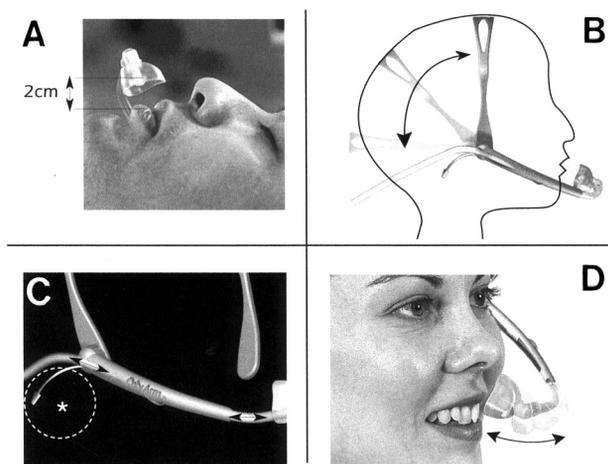


Fig. 1. Positioning of the OxyArm. A: Optimal positioning is 2 cm in front of the nose and mouth. B: The headset can be adjusted to various positions. C: A version of the OxyArm designed to allow capnography (this model was not used in this study); the carbon dioxide sampling line is within the dotted circle. D: The boom can be adjusted to position the diffuser.

livery system, and preliminary clinical studies showed that the OxyArm is functionally equivalent to the air-entrainment mask for low to medium flows.¹⁵ The present study was designed to compare oxygen saturation (measured via pulse oximetry [S_{pO_2}]) achieved with OxyArm versus NC at various oxygen flows.

Methods

Figure 1 shows the form and function of the OxyArm in seated and recumbent positions. A standard oxygen tube supplies the diffuser system through an adjustable boom that extends down the side of the face. The boom can be adjusted to position the diffuser. The optimum diffuser position is about 2 cm in front of the mouth and nose. Our preliminary evidence suggests that the unit can be displaced by up to 2 cm without noticeable effect on oxygen delivery efficiency, as measured by oxigraphy at the nasopharynx (unpublished data). The flexible head band that holds the device in place can also be adjusted for patient comfort. The entire OxyArm system is odorless and latex-free. A future model of the OxyArm will allow capnography by way of a carbon dioxide sampling line (Fig. 1c).

The study was conducted at the office of Sandy McDonald MD. Ten adults (ages 64 to 83) displaying chronic obstructive pulmonary disease and who were prescribed home supplemental oxygen therapy were studied after giving informed consent. Subjects were alert, seated, and under resting respiratory conditions. No instructions were given on breathing pattern. Medical grade oxygen was supplied at the flows and through the NC devices histor-

ically used by the patients. Blood oxygen saturation (measured via pulse oximetry [S_{pO_2}]) was measured at the left and right index fingers, using redundant recorders (AS/3, Datex-Ohmeda, Andover, Massachusetts) calibrated to the manufacturer's specifications. The mean of these 2 readings was recorded at 30-s intervals, over 5 minutes, incorporating the limitations of noise inherent to oximetry readings into the standard deviation of each patient's results. The NC were then replaced with the OxyArm for comparison at the same oxygen supply flow, with a 7-min interval to ensure stability before recording the OxyArm S_{pO_2} results. Direct comparison of the 2 systems was performed using paired, 2-sample *t* tests of the S_{pO_2} means. Differences were considered statistically significant if $p < 0.05$ (95% confidence).

Results

Table 1 shows the mean S_{pO_2} values and 95% confidence intervals from paired tests of the OxyArm and NC systems. Both systems maintained acceptable levels of oxygen saturation in the studied subjects with the oxygen flows studied. In 7 of the 10 subjects the mean S_{pO_2} sampled over periods of several minutes was the same with both devices at oxygen flows from 2 to 5 L/min, as indicated by the paired sample *t* test for means, in which $p > 0.05$. In 2 subjects, the OxyArm maintained higher S_{pO_2} (OxyArm 97.9 ± 0.3 vs NC 97.2 ± 0.4 , and OxyArm 98.8 ± 0.6 vs NC 98.0 ± 0.5 , $p < 0.01$). In 1 subject the OxyArm maintained a lower S_{pO_2} than the NC (OxyArm $91.1 \pm 0.5\%$ vs NC 92.8 ± 0.7 , $p < 0.01$).

Discussion

Evaluation of oxygen delivery systems for post-anesthetic and long-term applications should be based on adequacy of oxygen delivery, patient acceptability and compliance, ease of use, and cost-effectiveness. A variety of oxygen mask and NC designs are commonly used and have attractive safety profiles, albeit with known disadvantages.³⁻⁹ The OxyArm was designed to overcome some of these limitations while maintaining functional equivalence to predicate mask and NC devices.

Subjects were asked for anecdotal feedback concerning comfort and aesthetic considerations. Though this input was not specifically documented, most preferred the minimal contact design of the OxyArm and were generally indifferent to the appearance of either device.

This preliminary study suggests that the OxyArm is functionally equivalent to the NC system, maintaining the same or better oxygen saturation levels in 9 of 10 subjects studied. Moreover, the OxyArm was well tolerated by all subjects and is suited for both nose and mouth breathing. The minimal-contact design may improve patient compli-

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Table 1. Oxygen Saturation Levels With OxyArm Versus Nasal Cannulae

Subject	Sex	Age	Months On Oxygen	Device	Oxygen Flow (L/min)	Mean S_{pO_2} (%)	SD	95% CI	p
1	F	64	64	OA	4	91.1	0.5	90.9, 91.2	< 0.01
				NC	4	92.8	0.7	92.5, 93.0	
2	F	66	12	OA	2	95.6	0.5	95.5, 95.8	0.99
				NC	2	95.6	0.4	95.5, 95.8	
3	M	65	9	OA	3	97.4	0.5	97.2, 97.5	0.30
				NC	3	97.6	0.4	97.5, 97.7	
4	F	78	48	OA	3	96.5	0.5	96.4, 96.7	0.11
				NC	3	96.8	0.5	96.6, 97.0	
5	M	78	2	OA	2	97.1	0.4	97.0, 97.2	0.11
				NC	2	96.8	0.5	96.7, 97.0	
6	F	71	42	OA	5	95.7	0.6	95.5, 95.8	0.06
				NC	5	96.4	0.5	96.2, 96.5	
7	M	76	7	OA	2	97.9	0.3	97.8, 98.0	< 0.01
				NC	2	97.2	0.4	97.1, 97.3	
8	F	83	2	OA	3	98.8	0.6	98.6, 99.0	< 0.01
				NC	3	98.0	0.5	97.9, 98.1	
9	F	70	10	OA	2	95.0	0.2	94.9, 95.0	0.19
				NC	2	95.1	0.3	95.0, 95.2	
10	M	73	6	OA	3	89.1	0.5	88.9, 89.2	0.20
				NC	3	88.5	1.0	88.2, 88.8	

Blood oxygen saturation measured via pulse oximetry (S_{pO_2})

OA = OxyArm

NC = nasal cannulae

SD = standard deviation

CI = confidence interval

p was determined via paired-sample, 2-tailed *t* test for means at 95% confidence interval ($\alpha = 0.05$)

ance because of better comfort and other aesthetic considerations. Patient anxiety may be reduced because of the lack of facial contact. It has been shown previously that the OxyArm delivers the same or greater fraction of inspired oxygen (F_{IO_2}) at flows of 2–10 L/min.¹¹ Further studies are needed regarding the suitability of the OxyArm for long-term oxygen therapy.

A number of OxyArm designs are in development and clinical testing and are meant to address applications that were not the specific focus of this study. Models under development include one that allows reuse of the main headset structural elements and per-patient replacement of the oxygen diffuser, and a sedation model designed to mitigate displacement of the OxyArm during sleep. Though the present study shows that the OxyArm and NC are functionally equivalent in maintaining S_{pO_2} under the conditions studied, other conditions could be examined, such as comparative performance during exercise and sleep conditions, relative compliance, patient satisfaction, and other clinical applications such as conscious sedation. The cap-

nography model is currently undergoing clinical evaluation. The OxyArm represents the evolution of a therapy that has not changed substantially in several decades, and it is hoped that development of the OxyArm will stimulate further interest in this field.

Conclusions

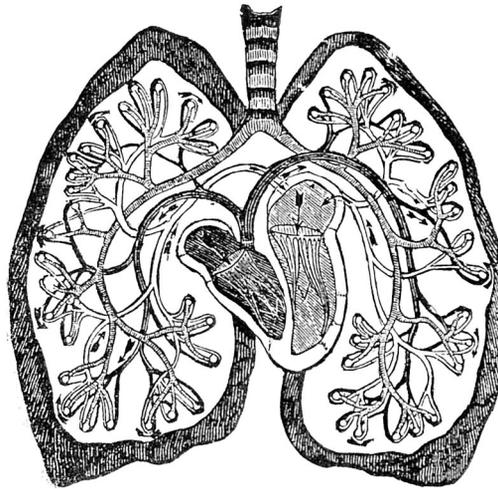
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