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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 FEV_1/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.

(Chest 1993; 103:1129-34)

RNC = reservoir nasal cannula; SNC = standard nasal cannula; SpO_2 = arterial hemoglobin oxygen saturation measured by pulse oximetry; Ti/Ttot = 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 million[3] (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 commerically, 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 (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.

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 PaO_2, percent oxyhemoglobin, percent carboxyhemoglobin, percent methemoglobin, $PaCO_2$, pH, HCO_3^-, FEV_1 (percent of predicted); forced vital capacity (FVC, percent of predicted); FEV_1/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 PaO_2 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 SpO_2 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.[2] In this study, we sought to determine empirically the oxygen flow required to maintain adequate oxygenation (SpO_2, 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 SpO_2 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 SpO_2 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 (PaO_2≤55 mm Hg or PaO_2 of 56 to 59 mm Hg with cor pulmonale or polycythemia [or both], FEV_1/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 SpO_2 throughout the night. This specific oximeter is designed to calculate the following summary statistics from continuous SpO_2 recordings: lowest SpO_2; mean SpO_2; percentage of time SpO_2 is less than 90 percent; percentage of time SpO_2 is less than 85 percent; percentage of time SpO_2 is less than 80 percent; and percentage of time SpO_2 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 $PaCO_2$ 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 SpO_2 Comparison*

	RNC			SNC		
		Mean SpO_2,%			Mean SpO_2,%	
Patient	Flow Rate, L/min	Seated at Rest	Supine	Flow Rate, L/min	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.

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normal aged population as found in the literature.[8]

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

Mean age, yr	65±7
Mean height, cm	177±7
Mean weight, kg	87±21
Mean room-air PaO_2, mm Hg	55±4
Mean FEV_1, % of predicted	34±17
Mean FVC, % of predicted	57±21
Mean FEV_1/FVC, %	44±12
Mean D, % of predicted	47±26
Mean TLC, L	6.18±1.7
Mean RV, L	3.58±1.4
Mean FRC, L	4.36±1.5
Mean Ti/Ttot (sitting at rest)	0.4±0.2
Mean Ti/Ttot (supine)	0.4±0.2
Mean respiratory rate (sitting at rest)	19±6
Mean respiratory rate (supine)	19±6
Current oxygen usage, h/day	16.5±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 SpO_2 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 PaO_2 before the study. The difference in room-air PaO_2 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 PaO_2 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 SpO_2 of 91 percent and 93 percent for the RNC and SNC, respectively (Fig 1). In 23 out of the 26 subjects (88 percent), mean SpO_2 during the use of the SNC was the same or higher than it was during use of the RNC (Fig 2). In addition, nocturnal SpO_2 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 SpO_2 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 $SpO_2 \geq 92$ percent; $SpO_2 \geq 90$ 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

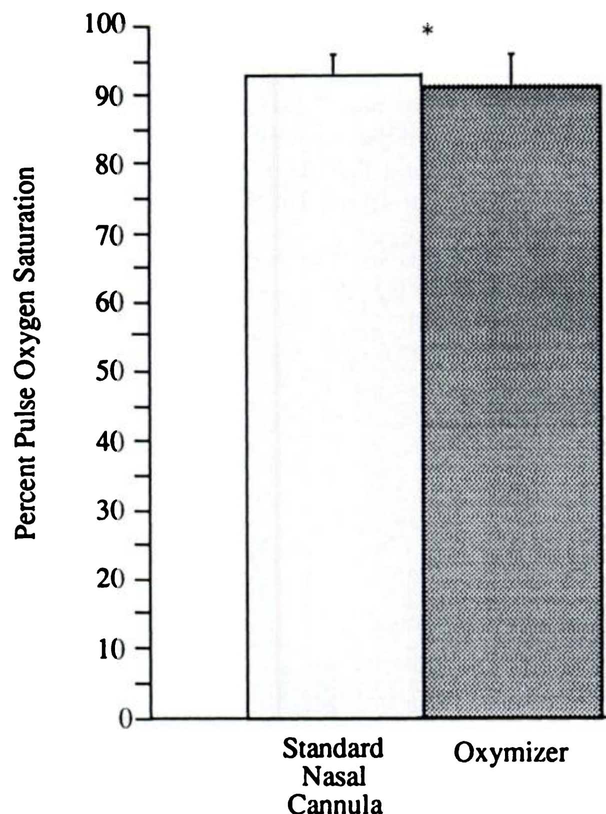

FIGURE 1. Mean (+SD) SpO_2 for two nights with oxygen supplied by SNC and RNC. Asterisk indicates $p<0.01$ for SNC versus RNC.

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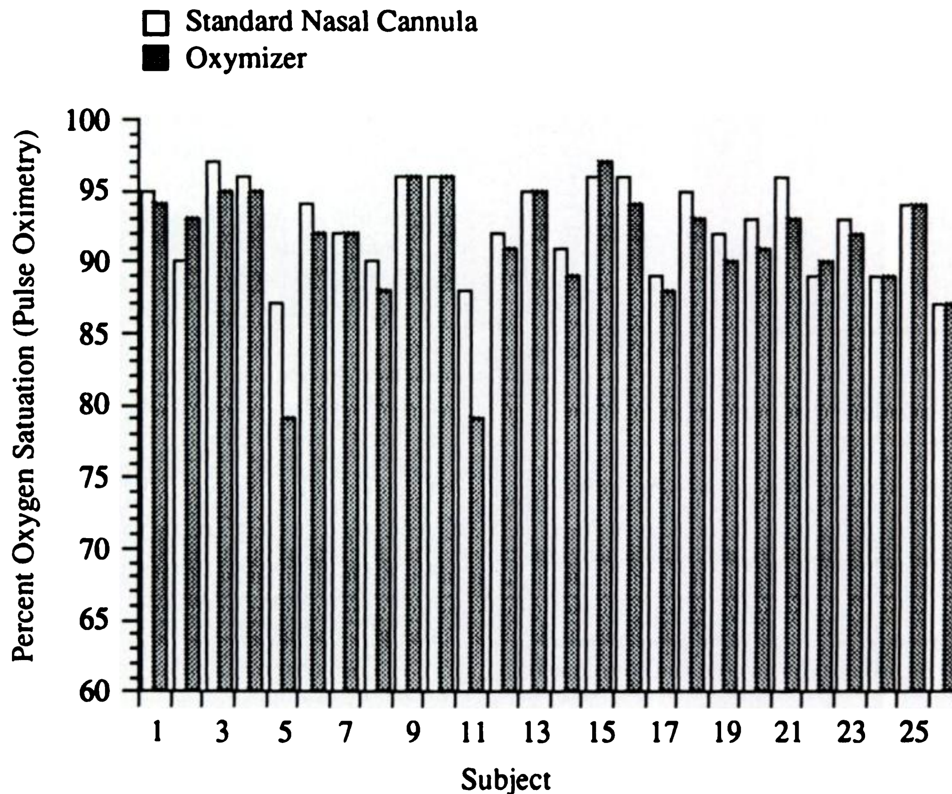

FIGURE 2. Mean SpO_2 for each subject with oxygen supplied by SNC or RNC.

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.

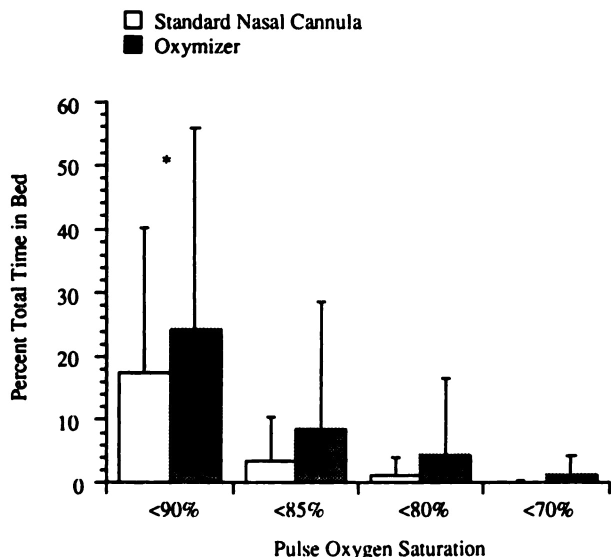

FIGURE 3. Mean (+SD) percentage of total time in bed below SpO_2 of 90, 85, 80, and 70 percent with oxygen supplied by SNC and RNC. Asterisk indicates $p<0.03$ for SNC versus RNC.

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 O_2 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.)

DISCUSSION

We conclude that the two devices are equally effective. The observed magnitude of difference in mean SpO_2 between the RNC and SNC (2 percent), while statistically significant, may be of little clinical relevance. Additionally, the mean difference in SpO_2 between devices fell within the range of measurement error for pulse oximetry. The mean percentage of total time in bed during which subjects' SpO_2 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 SpO_2 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

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Table 2—*Nighttime SpO_2 Readings*

Patient	RNC Flow Rate, L/min	Mean SpO_2, %		Percent of Time: SpO_2 <90%		SpO_2 <85%		SpO_2 <80%		SpO_2 <70%		RNC Category*
		SNC	RNC	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 SpO_2 within 2%; % of time SpO_2 <85%, <80%, or <70% the same; and less than 7% difference in % of time SpO_2 <90%); category 2, RNC performed *better than* SNC during sleep (mean SpO_2 achieved with RNC 2% or higher than mean SpO_2 achieved with SNC; and % of time SpO_2 <90%, <85%, <80%, or <70% greater with SNC); and category 3, RNC performed *worse than* SNC during sleep (mean SpO_2 achieved with RNC 2% or lower than mean SpO_2 achieved with SNC; % of time SpO_2 <90%, <85%, <80%, or <70% greater with RNC; and mean SpO_2 <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

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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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