

from 1043 patients who were screened for the study. Of these, 809 patients never entered the stabilization phase: 31% of them were found to have other major disease, 15% refused, 12% were discovered to have previously received chronic O₂ therapy, and in 21% the arterial PO₂ rose so that the patient was no longer eligible. The remainder of these 809 patients were ineligible for a variety of reasons, such as living too far from a study center. In all six centers, a total of only four patients fulfilled the entry criteria but were judged by the investigators to be "too sick" to undergo 3 weeks of observation off O₂. Thirty-one patients entered stabilization but did not complete it and were not randomized to the study. Failure of completion was chiefly due to an absence of informed consent or a rise in arterial PO₂ during stabilization such that the patient was ineligible.

Table 2 shows selected mean baseline characteristics of both nocturnal O₂ therapy and continuous O₂ therapy groups and indicates that they were comparable: The randomization process was successful. The average patient age was more than 65 years; most patients were male. They were hypoxemic with a slightly elevated hematocrit value and borderline CO₂ retention. Expiratory flow was severely compromised, and they were hyperinflated. Maximum exercise performance, as tested by bicycle ergometry, was sharply limited. The average patient

showed resting tachycardia, modest pulmonary hypertension, and increased pulmonary vascular resistance. During sleep, patients were hypoxemic while breathing air but generally not while breathing their prescribed dose of O₂. Neuropsychological test results showed that the average patient had impaired brain function; patients on continuous O₂ therapy appeared to be slightly less impaired than those on nocturnal O₂, the difference approaching significance when the overall clinical rating and the Russell-Neuringer average impairment index were considered. Quality of life measures indicated relatively low level of patient self-satisfaction, reduced physical and social capabilities, and increased levels of depression, anxiety, and hostility. More detailed analyses of these baseline data will be presented in other reports.

Compliance was assessed both by timers and by examining patient logs. The former was objective but systematically underestimated O₂ use by continuous O₂ therapy patients with portable systems. In nocturnal O₂ therapy patients, timer and log data were in excellent agreement, both indicating that more than 82% of the nocturnal O₂ therapy patients used 13 hours or less of O₂ per day. According to timers, nocturnal O₂ therapy patients averaged 12.0 h/d (SD = 2.5 h/d) whereas continuous O₂ therapy patients averaged 17.7 h/d (SD = 4.8 h/d). Figure 1 shows data from patient logs and indicates that

Table 2. Baseline Characteristics of Nocturnal O₂ Therapy and Continuous O₂ Therapy Groups

Characteristics*	Nocturnal O ₂ Therapy	Continuous O ₂ Therapy	P Value
General and cardiopulmonary characteristics			
Patients, no.†	102	101	
Age, yrs	65.7	65.2	0.72
Male, %†	80.4	77.2	0.58
White, %†	78.4	77.2	0.84
Pa _{O₂} , mm Hg	51.5	50.8	0.32
Pa _{CO₂} , mm Hg	43.9	43.4	0.70
pH	7.41	7.40	0.19
Hematocrit, %	47.3	47.7	0.60
FEV ₁ , % predicted	29.9	29.5	0.82
FVC, % predicted	53.6	52.6	0.70
FRC, % predicted	177.6	175.7	0.78
Mean sleep Sa _{O₂} , air, %	83.5	83.0	0.66
Mean sleep Sa _{O₂} , O ₂ , %	94.0	94.1	0.83
Maximum workload, air, W	37.3	37.5	0.95
Heart rate, min ⁻¹	92.6	93.1	0.83
Mean pulmonary artery pressure, mm Hg	29.0	30.0	0.58
Cardiac index, L/min·m ²	2.91	2.95	0.69
Pulmonary vascular resistance, dyne/s·cm ⁵	330	333	0.91
Neuropsychiatric characteristics‡			
Overall rating (3.5)	4.5	4.2	0.06
Halstead impairment index (0.63)	0.78	0.73	0.15
Russell-Neuringer average impairment index (1.8)	2.3	2.1	0.08
Brain age quotient (89)	75.4	80.4	0.11
Quality of life‡			
MMPI, average scales 0.9 (54.5)	60.9	61.4	0.68
SIP			
Physical scale (0.6)	20.5	19.8	0.78
Psychosocial scale (1.6)	23.9	20.5	0.22
POMS—mood disturbance (26.4)	48.4	49.7	0.76

* FEV₁ = forced expiratory volume in 1 second; FVC = forced vital capacity; FRC = functional residual capacity; MMPI = Minnesota Multiphasic Personality Inventory; SIP = Sickness Impact Profile; POMS = Profile of Mood States.

† All values reported for the two groups are mean values except numbers of subjects, sex, and race.

‡ Normal values are shown in parentheses.