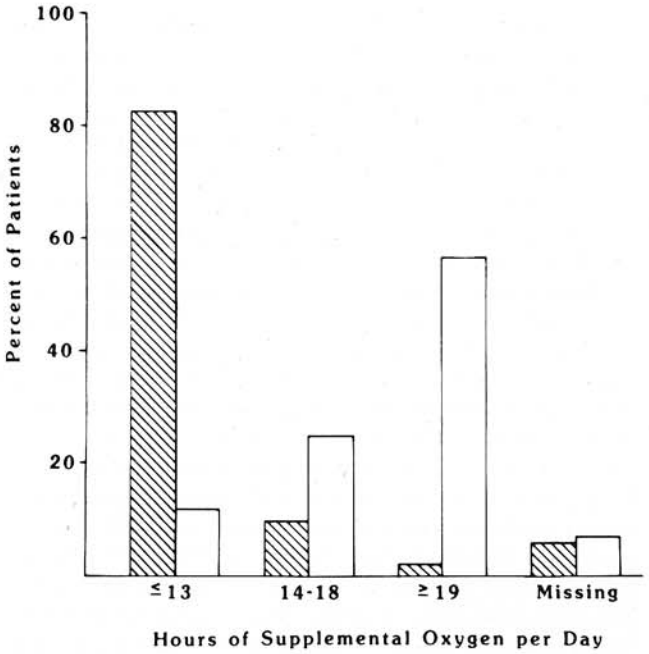

Figure 1. Compliance with treatment regimens as assessed by patient log, expressed as a frequency distribution of daily O_2 use. Hatched bars represent patients on nocturnal O_2 therapy, open bars, those on continuous O_2 therapy. "Missing" indicates patients in whom data are missing.

82% of nocturnal O_2 therapy patients used O_2 for 13 hours or less per day and that 56% of continuous O_2 therapy patients used O_2 for 19 or more hours per day.

The 203 patients were followed for an average of 19.3 months. Of the total group, 80 nocturnal O_2 and 87 continuous O_2 therapy patients were followed for 12 months and 29 nocturnal O_2 and 37 continuous O_2 therapy patients were followed for 24 months. Two continuous O_2 therapy patients were lost to follow-up 2 months before the trial was ended, one after 12 months of treatment and the other after 15 months. A total of 64 patients died, 41 in the nocturnal O_2 therapy group and 23 in the continuous O_2 therapy group. Life table cumulative survival rates, shown in Figure 2, indicate the pattern of mortality throughout the study period. Based on the Cox model, unadjusted for baseline characteristics, this difference in survival was significant ($P = 0.01$). The 12-month mortality was 20.6% (SE = 4.0%) in the nocturnal O_2 therapy group and 11.9% (SE = 3.2%) in the continuous O_2 therapy group, whereas the 24-month mortality was 40.8% (SE = 5.5%) and 22.4% (SE = 4.6%), respectively. Overall mortality was 31.5% for all patients and varied from 15.4% to 41.9% among centers. At all centers, mortality for the nocturnal O_2 therapy group exceeded that for the continuous O_2 therapy group. The relative risk of death for the nocturnal O_2 therapy group compared with the continuous O_2 therapy group was 1.94 with 95% confidence limits ranging from 1.17 to 3.24. The above analyses were done according to treatment assignment and did not consider compliance. However, compliance was very good, and compliance failure could not account for the difference between groups.

Mortality was examined in subgroups defined according to variables thought to be clinically important; the median overall baseline values of these variables were used to separate groups. Figure 3 shows mortality in patients with arterial P_{CO_2} equal to or greater than 43 mm Hg, the median value for all patients at baseline; survival was better in the continuous O_2 therapy group, and this difference was highly significant ($P < 0.002$). This and other selected baseline values are related to mortality in Table 3. In two other subgroups, those with low pH and those who showed high levels of mood disturbance such as depression and anxiety (Profile of Mood States test), the continuous O_2 therapy group demonstrated very significantly greater survival than the nocturnal O_2 therapy group. Also, in a number of other subgroups mortality differed ($0.01 < P < 0.05$). Patients with low FVC, high FRC, more severe nocturnal hypoxemia, low hematocrit values, and more severe indexes of brain dysfunction all tended to have lower mortality on continuous than on nocturnal O_2 therapy. The same was true of patients with pulmonary artery pressure and pulmonary vascular resistance values that were below the median and for those whose work capacity on the cycle ergometer was above the median.

Although patients on continuous O_2 therapy tended to be hospitalized less often and to have fewer long hospitalizations than nocturnal O_2 therapy patients, differences were not statistically significant.

The effects of treatment on the physiological and psychological variables listed in Table 2 were examined by comparing baseline and follow-up data in individual patients. For some variables, such as those resulting from cardiac catheterization, only 6-month follow-up data were available. For other indexes, such as arterial P_{O_2} and P_{CO_2}, results at 6 months, 12 months, and 18 months could be compared with baseline values. With the exception of hematocrit and pulmonary vascular resistance, none of the variables listed in Table 2 showed statistically significant changes that were dependent on treatment regimen. Hematocrit values fell more in patients on con-

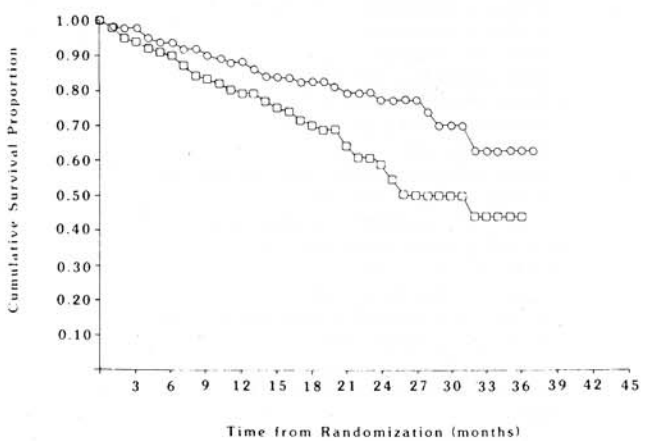

Figure 2. Overall mortality. Ordinate is fraction of patients surviving; abscissa is time from randomization or duration of treatment. Open circles represent continuous O_2 therapy group; squares represent nocturnal O_2 therapy group. Of the total group, 80 nocturnal O_2 and 87 continuous O_2 therapy patients were followed for 12 months, and 29 nocturnal O_2 and 37 continuous O_2 therapy patients were followed for 24 months.