

ORIGINAL ARTICLE

Randomized Trial of Nocturnal Oxygen in Chronic Obstructive Pulmonary Disease

Yves Lacasse, M.D., Frédéric Sériès, M.D., François Corbeil, M.D.,
 Marc Baltzan, M.D., Bruno Paradis, M.D., Paula Simão, M.D.,
 Araceli Abad Fernández, M.D., Cristóbal Esteban, M.D., Miguel Guimarães, M.D.,
 Jean Bourbeau, M.D., Shawn D. Aaron, M.D., Sarah Bernard, M.Sc.,
 and François Maltais, M.D., for the INOX Trial Group*

ABSTRACT

BACKGROUND

Long-term oxygen therapy improves survival in patients with chronic obstructive pulmonary disease (COPD) and chronic severe daytime hypoxemia. However, the efficacy of oxygen therapy for the management of isolated nocturnal hypoxemia is uncertain.

METHODS

We designed this double-blind, placebo-controlled, randomized trial to determine, in patients with COPD who have nocturnal arterial oxygen desaturation without qualifying for long-term oxygen therapy, whether nocturnal oxygen provided for a period of 3 to 4 years would decrease mortality or the worsening of disease such that patients meet current specifications for long-term oxygen therapy. Patients with an oxygen saturation of less than 90% for at least 30% of the recording time on nocturnal oximetry were assigned, in a 1:1 ratio, to receive either nocturnal oxygen or ambient air from a sham concentrator (placebo). The primary outcome was a composite of death from any cause or a requirement for long-term oxygen therapy as defined by the Nocturnal Oxygen Therapy Trial (NOTT) criteria in the intention-to-treat population.

RESULTS

Recruitment was stopped prematurely because of recruitment and retention difficulties after 243 patients, of a projected 600, had undergone randomization at 28 centers. At 3 years of follow-up, 39.0% of the patients assigned to nocturnal oxygen (48 of 123) and 42.0% of those assigned to placebo (50 of 119) met the NOTT-defined criteria for long-term oxygen therapy or had died (difference, -3.0 percentage points; 95% confidence interval, -15.1 to 9.1).

CONCLUSIONS

Our underpowered trial provides no indication that nocturnal oxygen has a positive or negative effect on survival or progression to long-term oxygen therapy in patients with COPD. (Funded by the Canadian Institutes of Health Research; INOX ClinicalTrials.gov number, NCT01044628.)

From Institut Universitaire de Cardiologie et de Pneumologie de Québec-Université Laval, Quebec, QC (Y.L., F.S., S.B., F.M.), Centre Hospitalier Affilié Universitaire de Trois-Rivières, Trois-Rivières, QC (F.C.), Mount Sinai Hospital, McGill University (M.B.), and Montreal Chest Institute, Research Institute of the McGill University Health Centre and McGill University (J.B.), Montreal, Centre Intégré de Santé et de Services Sociaux de Laval, Laval, QC (B.P.), and the Ottawa Hospital Research Institute, University of Ottawa, Ottawa (S.D.A.) — all in Canada; Hospital Pedro Hispano—Unidade Local de Saúde de Matosinhos, Matosinhos (P.S.), and Centro Hospitalar Vila Nova de Gaia—Espinho, Vila Nova de Gaia (M.G.) — both in Portugal; and Hospital Universitario de Getafe, Getafe (A.A.F.), and Hospital Galdakao, Servicio Vasco de Salud—Osakidetza, Bizkaia (C.E.) — both in Spain. Address reprint requests to Dr. Lacasse at Centre de Pneumologie, Institut Universitaire de Cardiologie et de Pneumologie de Québec, 2725 Chemin Sainte-Foy, Quebec, QC G1V 4G5, Canada, or at yves.lacasse@med.ulaval.ca.

*A complete list of the investigators in the INOX Trial Group is provided in the Supplementary Appendix, available at NEJM.org.

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