Pulmonary Function After Hyperbaric Oxygen Therapy

NCT05088772

2023-Jul-09

Study design and participants

We conducted a retrospective analysis of prospectively collected data on a cohort of patients undergoing HBOT at the University Health Network's Hyperbaric Medicine Unit in Toronto, ON, Canada, between February 2016 and June 2021. All studied patients provided written consent to undergo HBOT (for a variety of clinical indications), and were scheduled to receive at least ten cycles of treatment at our large referral center during this timeframe. Patients underwent PFT assessment before starting HBOT and following every 20 treatment sessions thereafter.

Research ethics approval for the analysis of these data was provided by the University Health Network (Toronto, ON) Research Ethics Board (CAPCR ID: 19-5081.1). Data were collected retrospectively from the electronic records of enrolled patients, and comprised demographic information, HBOT indication and protocol, treatment complications, and PFT results immediately before the first HBOT session and following every subsequent 20 treatments. The protocol was retrospectively registered during the data collection stage and prior to analysis on Clinicaltrials.gov (trial ID: NCT05088772). We followed the STROBE guidelines for reporting observational cohort studies (S2 Table) [11].

Hyperbaric oxygen therapy protocol

The HBOT protocol utilized at our center has been previously described [12]. HBOT was performed with 100% O_2 at a pressure of 2.4 or 2.0 ATA (243 or 203 kPa) for 90 minutes, with 1-2 air breaks (0.21 fraction of inspired O_2 at the same ATA) per session, five times weekly in one of three mono-place chambers (Sechrist 3600H and Sechrist 4100H, Sechrist Industries Inc.,

Anaheim, CA, USA; PAH-S1-3200, Pan-America Hyperbarics Inc., Plano, TX, USA) or through a plastic hood in a multi-place chamber (rectangular Hyperbaric System, Fink Engineering PTY-LTD, Warana, Australia).

Pulmonary function testing protocol

Bedside spirometry was performed by a trained respiratory therapist using a KoKo Trek USB Spirometer software and pneumotachometer (KoKo, USA). Pulmonary function tests were completed at the time of consultation (prior to the first HBOT treatment) and following every 20 treatments thereafter. In rare cases when PFTs could not be obtained on the exact date of a 20^{th}, 40^{th}, or 60^{th} treatment (e.g., due to equipment limitations), they were obtained on the nearest possible date of another treatment and rounded to an increment of 20 at the time of data analysis. The spirometry equipment was calibrated at the beginning of each day. Patients were tested in a seated position with nose clips, in accordance with American Thoracic Society testing criteria [13], and results were compared against Knudson reference values [14] to determine their percentage of predicted values based on age, sex, and height. To capture potential restrictive, obstructive, and effort-independent changes, three markers of dynamic lung function were recorded: FEV_1% (percentage of predicted FEV_1), FVC% (percentage of predicted FVC), and FEF_{25-75}% (percentage of predicted FEF_{25-75}). The data utilized in this study comprise the highest readings for each of these variables from three satisfactory forced expiratory maneuvers performed as part of each PFT assessment. The primary outcome of this study was change in spirometry performance over the course of HBOT. We additionally classified the degree of any baseline PFT abnormalities on the basis of each independent parameter's deviation from the

predicted value, designating mild abnormality as 70-79%, moderate abnormality as 60-69%, and severe abnormality as less than 60%.

Data collection and statistical analysis

Patient demographic data and past medical history characteristics were summarized using descriptive statistics, and continuous data were expressed as means ± standard deviations. Linear mixed effect regression models were used to estimate the adjusted sample mean scores of PFT outcomes FEV_1%, FVC%, and FEF_{25-75}% at each timepoint for the cohort. Timepoint was included as the fixed effect and individual subject as the random effect for each outcome for the overall cohort. PFT outcomes were also modeled for subgroups by timepoint interaction for pre-existing respiratory disease, smoking status, and treatment pressure (in ATA). Similarly, individual subjects were included as random effects. The maximum likelihood estimation was used to prepare the mixed models and analyzed under the intention-to-treat principal. Post-hoc pairwise comparisons between timepoints were conducted for each grouping of pre-existing respiratory disease, smoking status, and treatment pressure, for each PFT variable. Pairwise comparisons were adjusted using Tukey's HSD. The alpha was set to 0.05. All analyses were performed using R version 4.0.3.

Objectives

The primary objective of this study was to evaluate changes in series of pulmonary function tests (PFTs) performed over the course of recurrent HBOT exposures. A secondary study outcome was the incidence of pulmonary complications such as lung barotrauma.