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An international phase iii randomised trial on the efficacy of helium/oxygen during spontaneous breathing and intermittent non-invasive ventilation for severe exacerbations of chronic obstructive pulmonary disease (the E.C.H.O.^{ICU}trial)

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Introduction

Due to its reduced density, Helium/Oxygen (He/O_2) reduces the work of breathing, intrinsic PEEP and hypercapnia more than Air/O_2 during non-invasive ventilation (NIV) in COPD exacerbations [1,2]. Two prospective, randomized multicenter trials were inconclusive in showing a benefit of He/O_2 NIV on outcome (intubation, mortality, length of stay (LOS) in ICU) but were potentially underpowered [3,4].

Objectives

To evaluate whether 72-hr continuous He/O_2 during both spontaneous breathing and NIV is superior to Air/O_2 in reducing NIV failure (intubation or mortality during ICU stay) in severe hypercapnic COPD exacerbations. Secondary outcomes included physiological parameters, duration of ventilation, ICU and hospital LOS, 6-month recurrence and rehospitalization rates.

Methods

Prospective, randomized multicenter (16 centers in 6 countries) trial, comparing the two gas mixtures for a maximum of 72 hours. Hypothesis was that He/O_2 would reduce intubation rate from 25% to 15%, resulting in a total sample size of 670 patients. Spontaneous breathing and NIV were applied with specific devices for He/O_2. Same ventilator was used in both arms.

Results

The trial was stopped prematurely for futility (low intubation rate reported by the adjudication committee). 445 patients were included (mean ± SD 68 ± 11 yrs; M:F 69:31%; BMI 26 ± 6 kg/m^2; SAPS 3 49 ± 8; Resp rate (RR) 29 ± 6/min - PaO_2 75 ± 36 mmHg; $PaCO_2$ 69 ± 16 mmHg; pH 7.30 ± 0.06 - intention-to-treat data set), with no baseline difference between He/O_2 vs. Air/O_2. The primary outcome was negative (Figure 1) and baseline pH was the only significant predictor of NIV failure. NIV failure occurred in the first 72 hours (while receiving the study treatment) in 58% of failures with He/O_2 and 84% with Air/O_2 ($p = 0.97$). RR (Figure 2), pH, $PaCO_2$ and encephalopathy improved faster and with greater magnitude with He/O_2

Conclusions

NIV failure rate was not reduced by He/O_2 administered during NIV and spontaneous breathing for up to 72 hrs. Failure rate was low in both groups, reflecting the current efficacy of NIV in decompensated COPD. However, He/O_2 led to improved physiological response, thus confirming previous results, and a shorter duration of invasive ventilation and ICU stay in patients with NIV failure.

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Mean ± SD	Air/O_2 (220 pts)	He/O_2 (225 pts)	p
NIV failure *n (%)*	32 (14.5)	33 (14.7)	0.97
Cumulative duration of invasive ventilation after NIV failure *d*	13.6 ± 12.6	7.4 ± 7.6	0.02
LOS in ICU -all pts *d*	8.7 ± 6.7	10.1 ± 11.6	NS
LOS in ICU after NIV failure *d*	26.7 ± 21.0	15.8 ± 10.9	0.01
ICU mortality all pts *n (%)*	14 (6.4)	12 (5.3)	NS
6-mo. mortality *n (%)*	35 (15.9)	42 (17.8)	NS

Figure 1

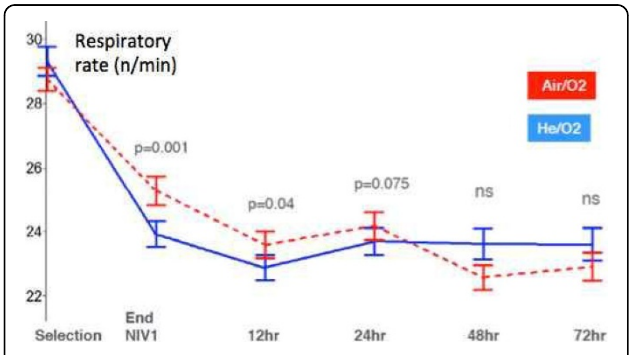

Figure 2

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