

Multicentric international randomized controlled study.

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Introduction

Oxygen therapy is commonly administered in critical care and emergency medicine. Its benefits and potential side-effects are well known, but compliance to recommendations remains dependent on staff workload. We developed FreeO₂, an innovative device that automatically titrates every seconds oxygen flow delivered through nasal cannulas or masks to achieve the SpO₂ target set by the clinician. The aim of this study was to compare FreeO₂ with oxygen manual adjustment, in patient admitted to the emergency department (ED) for acute respiratory failure (ARF).

Methods NCT02027181

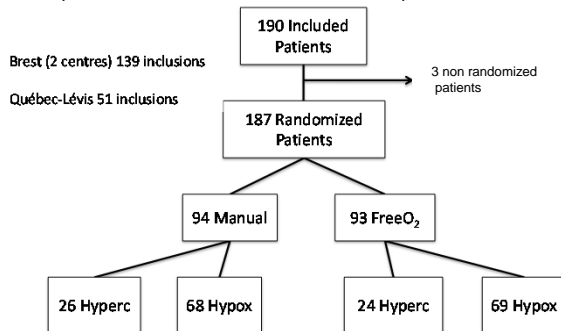


We conducted a multicentre randomized controlled study. Inclusion criteria were admission to ED for ARF requiring O₂ ≥ 3L/min. Main exclusion criteria were O₂ ≥ 15 L/min, immediate need for ventilatory support. After inclusion, patients were randomized to either FreeO₂ or conventional O₂ manual adjustment during 3 hours. In both group, SpO₂ was continuously monitored with the same oxymeter.

The randomization was web-based and stratified for the type of respiratory failure (hypoxemia/hypercapnia) and the centre. Primary endpoint was the % of time within predefined SpO₂ target (92-96% for hypoxemic patients; 88-92% for hypercapnic patients). Secondary endpoints were: frequency of severe hypoxemia (SpO₂ < 85%) and hyperoxia (SpO₂ > 98%), total O₂ duration, ventilator support use, ICU admissions, ICU and hospital LOS. Based on preliminary data, we anticipated a % time within SpO₂ target ≥ 70% under the automated system, as compared to 60% under conventional oxygen. A sample of 190 patients was required to show superiority of automated oxygenation with a power of 80 %.

Results

190 patients were included in the study in 4 centres from 08/2011 to 10/2014



	Manual (n=94)	FreeO ₂ (n=93)
Age (years)	77 ± 12	75 ± 13
Gender (Men)	51%	56%
O ₂ Flow (L/min)	5.5 ± 3.1	6.2 ± 3.1
SpO ₂ (%)	95 ± 4	95 ± 3
HR (c/min)	93 ± 22	91 ± 22
RR (c/min)	24 ± 4	25 ± 6
MAP (mmHg)	90 ± 14	89 ± 17
COPD (%)	38.3	31.5
LTOT (%)	8.5	9.8
Home NIV (%)	1.1	4.3

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Results

Figure 1: percentage of time in the SpO₂ target

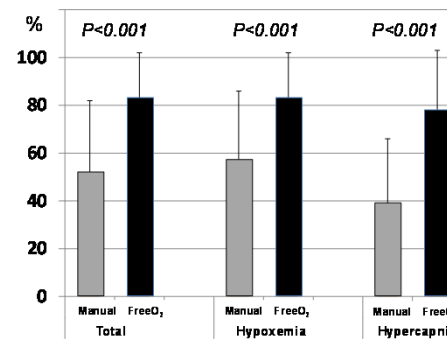


Figure 2: percentage of time with hyperoxia (SpO₂ ≥ 98%)

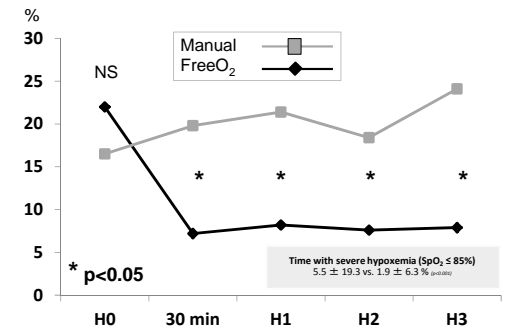


Figure 3: Duration of O₂ therapy during study / hospitalization

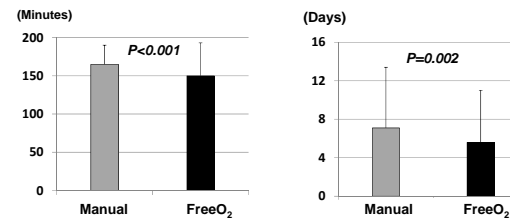


Figure 4: % of patients with O₂ flow reduction > 50%

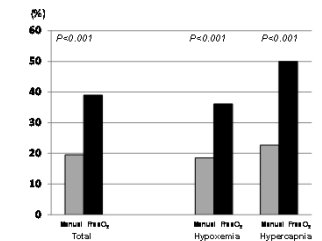
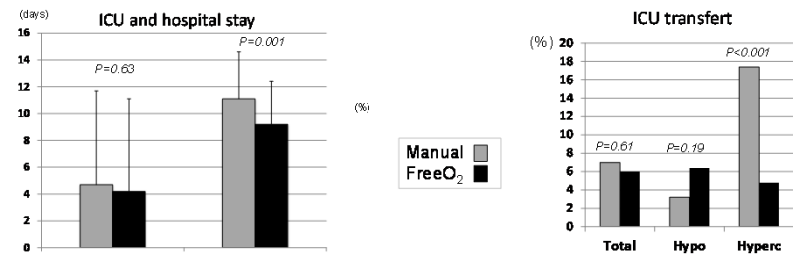


Figure 5: ICU & Hospital length of stay



Conclusions

The automation of oxygen therapy with FreeO₂ at the ED improves the oxygenation parameters with more time in the SpO₂ target, less desaturation and less hyperoxia. FreeO₂ may reduce staff workload and improve the compliance to recommendations for oxygen administration with potential related clinical benefits.