Oxygen titration and weaning with FreeO$_2$ in COPD patients hospitalized for exacerbation. A randomized controlled pilot study

François Lellouche[1,2], Pierre-Alexandre Bouchard[1], Maude Roberge[1], Guillaume Babin[1], Erwan L'Her[1,2], François Maltais[1], Yves Lacasse[1]

[1]Centre de recherche de l'Institut Universitaire de Cardiologie et de Pneumologie de Québec, Université Laval, Québec, Canada, [2]Oxynov. Inc, Québec, Canada

Introduction

Oxygen therapy is one of the most frequently used treatments on the respiratory ward. Compliance to practices guidelines is sub-optimal and time consuming. Clinicians are more concerned by desaturation than by hyperoxia, leading to the maintenance of higher than required oxygen flows. We have developed an innovative device (FreeO$_2$) that automatically adjusts the oxygen flow to reduce hyperoxia and hypoxemia and to automatically wean the oxygen. With FreeO$_2$, oxygen flows are titrated every second to maintain a constant SpO$_2$ at a target set by the physicians. We tested the feasibility of using such device in patients hospitalized for COPD exacerbations.

Methods NCT01393015

We have conducted a pilot randomized controlled study comparing usual O$_2$ administration and automated O$_2$ adjustment with FreeO$_2$ at the respirology department of our institution. The study was conducted in patients hospitalized with COPD exacerbation and requiring oxygen therapy. Inclusion criterion were the following: age ≥ 40 years, smoker ≥ 10 pack/year, acute exacerbation (<15 days), O$_2$ < 8L/min for SpO$_2$ ≥ 92%; Exclusion criterion were: admission > 48h, infection/colonisation with MDR bacteria, patient on NIV, cognitive impairment, lack of available FreeO$_2$ prototype. Patients were randomized to recieve usual care for oxygen administration or automated titration by FreeO$_2$ with remote monitoring at the nursing station of SpO$_2$ and oxygen flow rate. The setting of the study with FreeO$_2$ prototypes can be viewed at

http://www.youtube.com/watch?v=JmGy8--gRt0

The main objective of the study was to evaluate if FreeO$_2$ could be used in daily practice and if it was accepted by the caregivers (primary outcome).

Daily, we evaluated the perception of oxygen management in both groups by nurses and physicians with a visual analogue scale Lickert type (0 to 10 scale).

Patients in both groups had continuous monitoring of SpO$_2$, respiratory and heart rate and EtCO$_2$. The secondary outcomes were (i) the time in the SpO$_2$ target as defined by the physician in charge of each patient ± 2% (ii) the time with severe desaturation (SpO$_2$ below 85%) (iii) the time with hyperoxia (SpO$_2$ > 5% above the target) (iv) oxygen therapy duration (v) hospital length of stay.

Grants: Fonds de Recherche en Santé du Québec, Canadian Foundation for Innovation, IUCPQ foundation

Results

Table 1: Patient's characteristics (at inclusion)

	FreeO$_2$ (n=25)	Control (n=25)
Age (year)	71±8	73±8
FEV$_1$ (L)	1.0±0.5	1.0±0.5
FEV$_1$ (% th.)	0.38±0.18	0.43±0.24
FEV$_1$/VC (%)	0.45±0.12	0.49±0.13
O$_2$ Flow (L/min)	2±1	2±1
pH	7.40±0.05	7.39±0.05
PaCO$_2$ (mmHg)	46±12	46±11
HCO$_3^-$ (mmoles/l)	28±5	27±5
SpO$_2$ (%)	93±2	93±2
Temperature (°C)	36.6±0.6	36.7±0.6
Respiratory rate (c/min)	22±3	21±2
ED admission to inclusion (days)	0.6±0.7	0.6±1.1

Table 2: Primary outcome

	FreeO$_2$ (n=25)	Control (n=25)	P value
O$_2$ adjustment NURSES (0 to 10 scale)	8.9 ± 1.5	8.8 ± 1.8	0.46
O$_2$ monitoring NURSES (0 to 10 scale)	8.9 ± 1.4	8.7 ± 2.0	0.19
O$_2$ adjustment PHYSICIANS (0 to 10 scale)	8.2 ± 2.2	7.8 ± 2.1	0.48
O$_2$ monitoring PHYSICIANS (0 to 10 scale)	8.2 ± 2.2	6.7 ± 3.2	0.07
Number of patients who completed the study (n, %)	20 (80)	20 (80)	1

Table 3: Clinical outcome

	FreeO$_2$ (n=25)	Control (n=25)	P value
Duration of O$_2$ administration (days)	4.0±2.1	5.8±9.9	0.14
Hospital length of stay			
Inclusion to hosp. discharge (days)	5.8±4.4	8.4±6.0	0.05
Admission to hosp. discharge (days)	6.7±4.3	9.5±6.0	0.05
Complications			
NIV (n)	0	1	0.48
ICU transfert (n)	0	1	0.48
Death (n)	1	1	1
Readmissions (within 30 days) (n)	6	6	1

Table 4: Oxygenation and capillary blood gases

		FreeO$_2$ (n=25)	Control (n=25)	P value
SpO$_2$ target (%) *		90.0±1.2	90.1±1.0	0.89
Mean SpO$_2$ (%)		90.9±1.2	91.9±1.2	<0.001
% of time in the target ± 2%		81.2±15.9	51.3±19.7	<0.001
% of time > target + 5%		1.5±1.9	10.4±10.3	<0.001
% of time SpO$_2$ < 85 %		0.2±0.2	2.3±2.7	0.001
Mean O$_2$ flow (L/min)		0.7±0.7	1.2±1.0	0.06
% of time with SpO$_2$ signal available		90.4±7.6	82.4±12.7	0.01
Day 3	pH	7.42±0.03	7.41±0.05	0.33
	PaCO$_2$	45±7	46±10	0.62
	HCO$_3^-$	29±4	29±5	0.94
	O$_2$ flow (L/min)	0±0	1.3±1.3	0.08
Day 7	pH	7.43±0.02	7.42±0.06	0.53
	PaCO$_2$	40±4	47±13	0.14
	HCO$_3^-$	27±2	30±6	0.20
	O$_2$ flow (L/min)	0±0	0.5±0.9	0.49

*Specified by the physician in charge at inclusion

Conclusions

-This pilot study demonstrates that automated oxygen titration and weaning by FreeO$_2$ is feasible in patients hospitalized with acute COPD exacerbations.

- Automated oxygen adjustment and remote monitoring was well accepted by nurses and by physicians. However, 20% of the patients did not complete the study in both groups. Improvement of the device will allow better acceptance by the patients.

- FreeO$_2$ provided a better ability to maintain SpO$_2$ in the target range, a reduction in duration of hyperoxia and desaturation. We also observed a trend towards reduction of oxygen therapy duration, and a trend for PaCO$_2$ reduction at Day 7.

- These data demonstrate a potential to reduce the hospitalization length of stay, although the study was not designed for this evaluation.