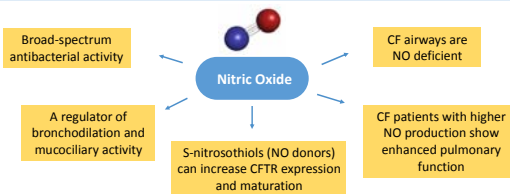


Nitric Oxide Inhalation in Cystic Fibrosis Patients Infected with *Mycobacterium Abscessus* Complex: A Prospective, Open-Labeled, Multi-Center Pilot Study

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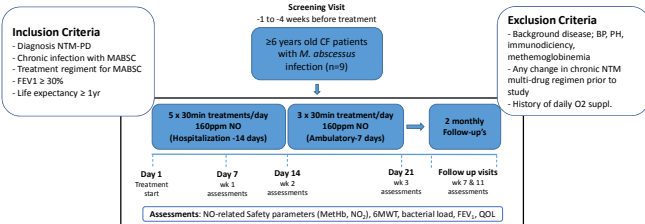
BACKGROUND



Potential benefits of Inhaled Nitric Oxide (NO) therapy in CF patients.

SUBJECTS & METHODS

We conducted a prospective open-label multi-centre study to evaluate the safety and efficacy of inhaled NO (160ppm) in persistent NTM-CF patients.



	Objective	Endpoint	Baseline Characteristics
Primary	Safety and tolerability	NO-related SAEs	Gender: 5 female, 4 male
Secondary	6MWD	6MWD	Age (Years, Mean ± SD): 22.70 ± 6.18
	M. abscessus load	Sputum M. abscessus load	Background Disease: All with CF-NTM-PD (MABSC)
Additional data	Lung Function - FEV1	FEV1	Current Medication: Not changed (NO was add-on)
	CF-related pathogens burden	CFU/ml of CF-related pathogens	

RESULTS

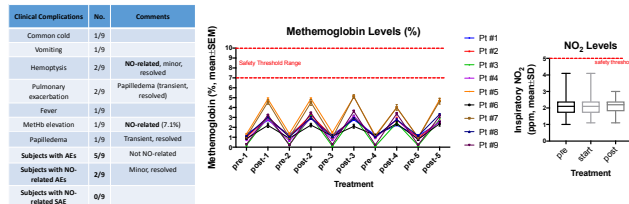


Fig. 1. Inhaled NO at 160ppm was safe and well tolerated by CF-NTM patients. No NO-related SAEs were reported. MetHb and NO₂ levels remained within the accepted ranges (7% and 5ppm, respectively) after NO treatment. MetHb returned to baseline shortly after each NO treatment. Vital signs were stable.

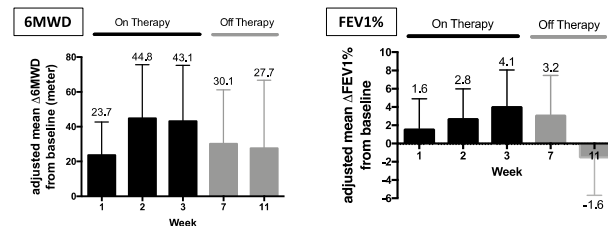


Fig. 2. Inhaled NO (160ppm) improved 6MWD and Lung Function in CF-NTM patients. 6-min walk distant (6MWD) improved in 6 out of 9 CF-NTM patients treated with inhaled NO (left graph). Lung function measured by FEV1% improved in 5/9 treated patients (right graph). The mean values at the end of each treatment period are shown at the top of each bar.

RESULTS

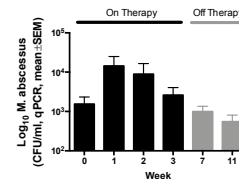


Fig. 3. Inhaled NO treatment led to reductions in sputum *M. abscessus* load. *M. abscessus* DNA, detected by qPCR, increased during initial treatment and then reduced in 5/9 patients (> 1-log) at follow-up. 1/9 patient showed complete culture eradication.

Out of 4 CF-NTM patients with chronic pseudomonas aeruginosa infection, 2 patients experienced negative culture at follow up and a third showed >2-log reduction.

CONCLUSION

- High-dose inhaled NO (160ppm) is safe and tolerable in CF patients.
- High-dose inhaled NO (160ppm) may improve lung function.
- Increase in sample size may achieve statistical significance in 6MWD improvement.
- High-dose inhaled NO may reduce bacterial burden in CF patients with *M. abscessus* and/or *P. aeruginosa* infection.
- Longer treatment duration (and/or higher dose) is warranted to improve the effect of inhaled NO therapy in CF-NTM-PD.

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