STIT-1: Evaluation of safety and efficacy of shorttime TNI® treatment in patients with COPD – First interim analysis

H. Vogelsinger[1], M. Halank[2], S. Braun[2], S. Ott[3], S. Desole[1], T.Geiser[3], C.M. Kaehler[1]
[1] Pneumology Service, Department of General Internal Medicine, Medical University of Innsbruck
[2] Pneumologie, Medizinische Klinik und Poliklinik I, University Hospital Carl Gustav Carus Dresden
[3] Klinik und Poliklinik für Pneumologie, Universitätsspital Bern, Inselspital

Background

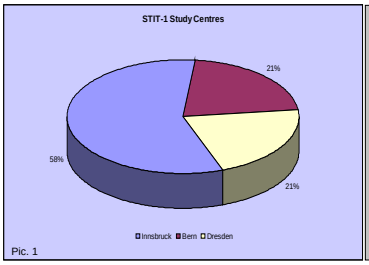
COPD is projected to be the third leading cause of death worldwide by 2020. Long-term oxygen therapy (LTOT) is one of the established treatment strategies in the GOLD algorithm.
Nasal insufflation of warm, humidified air at a high flow rate (TNI®) is a new and simplified method in non-invasive ventilation.
Until now, this method (TNI®) was successfully evaluated in the treatment of OSA patients (1). However, no data on safety and efficacy of TNI® in COPD patients are currently available.

Aim

Our multicenter (Pic. 1), controlled study was designed to examine the safety of trans-nasal high flow oxygen insufflation by TNI® in patients with COPD (GOLD °III/IV).
The study was further conducted to assess a possible reduction of necessary oxygen delivery in LTOT patients and its effect on hyperinflation.

Methods

The trial has been approved by the national ethic committees.
Stable patients with COPD °III/IV with indication for LTOT (ATS/ERS criteria) are enrolled. The following inclusion criteria have to be met: age 30-80, stable disease without exacerbation for at least 14 days prior inclusion, Hb > 100 g/l, a normal paCO2, RV/TLC < 0,65 and no current participation in another study.
So far 14 subjects were recruited (Tab. 1): 14 males, age 68.8 ± 5.2 yr, FEV1 ranged from 23 to 49 % predicted. All patients were explored for standard LTOT treatment and for the new TNI® method. Oxygen supplementation was performed in 10 min intervals each with an augmentation of 0.5 - 1 L/min until a pO2 ≥ 60mmHg was achieved.
Using the high flow strategy of TNI®, oxygen was mixed with warm and humidified air and a constant flow rate of 15 L/min which was administered through an open nasal cannula.
Blood gas analysis and lung function tests were performed according to the protocol.

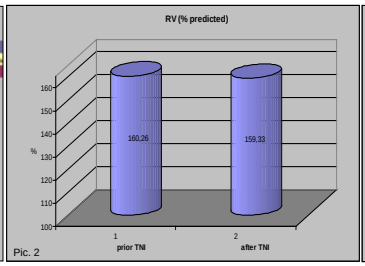


Pic. 1

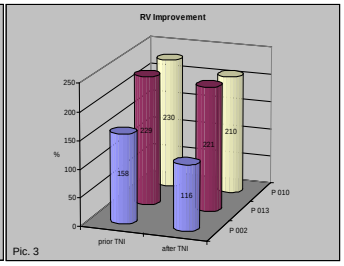
Demographic Data

Patient	Age	Sex	FEV1 (%)	LTOT (l O2)	
001	70	m	38	1,5	Ibk.
002	63	m	49	2,5	Dresden
003	60	m	34	3	Bern
004	72	m	23	2	
005	72	m	45	6	
006	65	m	45	6	
007	74	m	43	2,5	
008	69	m	37	2,5	
009	60	m	36	5	
010	69	m	25	1	
011	65	m	36	3,5	
012	79	m	49	0,5	
013	69	m	27	0,5	
014	73	m	48	8	
MV	68,8	14 m	36,3	3,2	
SD	5,1		8,9	2,3	

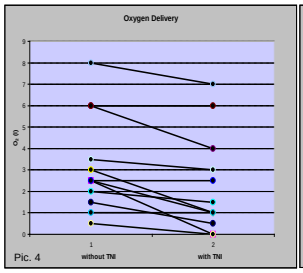
Tab. 1



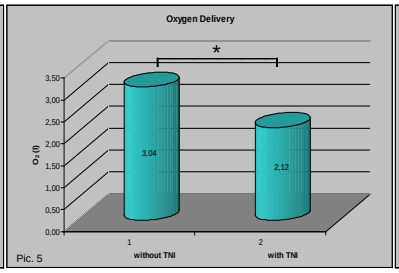
Pic. 2



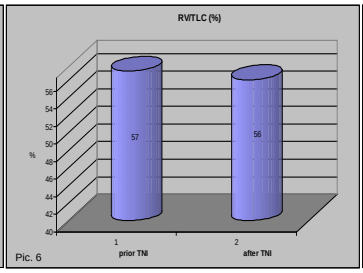
Pic. 3



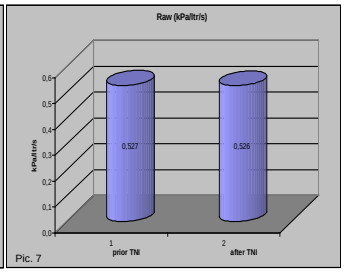
Pic. 4



Pic. 5



Pic. 6



Pic. 7

Results

Concerning safety TNI® delivery was well tolerated in all patients and no significant differences were found for several spirometric parameters tested (RV, TLC, VC, IC, ERV, Raw, FEV1, DLCO) (Pic. 2, 3, 6, 7).
Furthermore, the necessary oxygen delivery to reach a sufficient paO2 in COPD patients was significantly lower by using the TNI® system (- 0.92 ± 0.84 L/min, p = 0.003*) compared to conventional oxygen administration (Pic. 4, 5)

Statistics were performed with SPSS using Wilcoxon analysis.

Conclusion

In conclusion, we can postulate that treatment with TNI® seems to be safe in patients with COPD °III/IV and that the necessary oxygen delivery in LTOT patients can be reduced significantly.

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References: (1) McGinley B et al (2007): "A Nasal Cannula Can Be Used to Treat Obstructive Sleep Apnea, Am. J. Respir. Crit. Care Med. 176(2):194-200.

Correspondence: Prof. Dr. Christian M. Kähler - Medical University of Innsbruck - Anichstrasse 35; A-6020 Innsbruck - e-mail: c.m.kaehler@i-med.ac.at